

US3842040 (Prod: New Jersey Medical School)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:32:45

All time stamps listed in this document are displayed in GMT

US3842040

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

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[Participant ID](#)

US3842040

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

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US3842040

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:47:43

Generated On: 12 Aug 2021 13:32:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3842040

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	49
Age Units	YEARS
Age (Derived)	49
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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 18:47:40

Generated On: 12 Aug 2021 13:32:45

Date of Informed Consent ( <i>dd MMM yyyy</i> )	18 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

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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 18:47:40

Generated On: 12 Aug 2021 13:32:45

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:45

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:45

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

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Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:32:45

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

US3842040

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:32:45

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

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Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:32:45

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:32:45

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

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Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:32:45

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:32:45

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:32:45

Condition	OCCASIONAL TENSION HEADACHE
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Start Year (derived)	1979
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:32:45

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

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Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:32:45

Condition	BLEPHAROSPASM
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:32:45

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

US3842040

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:47:43

Generated On: 12 Aug 2021 13:32:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	18 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:42 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:42
Height ( <i>xxx.x</i> )	158 cm
Weight ( <i>xxx.x</i> )	81 kg
BMI ( <i>xxx.x</i> )	32.44672 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)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 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: Childbearing Potential

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Date of assessment (dd MMM yyyy) 18 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☐  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	18 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

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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**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 18:47:41

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<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)	True
<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 18:47:43

Generated On: 12 Aug 2021 13:32:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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 18:47:41

Generated On: 12 Aug 2021 13:32:45

What was the date of randomization? (dd MMM yyyy) 18 SEP 2020

What was the participant's randomization number? 146269

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) 16 Feb 2021 18:47:44

Generated On: 12 Aug 2021 13:32:45

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) 16 Feb 2021 18:47:44

Generated On: 12 Aug 2021 13:32:45

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)	18 SEP 2020
Time of assessment (00:00-23:59)	14:42 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:42
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:47:44

Generated On: 12 Aug 2021 13:32:45

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)	18 SEP 2020
Time of assessment (00:00-23:59)	17:07 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 17:07
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 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 18:47:40

Generated On: 12 Aug 2021 13:32:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 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: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 16:36 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 16:36

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 18:47:39

Generated On: 12 Aug 2021 13:32:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

15:40 (24 HR)

Collection date and time (derived)

18 SEP 2020 15:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:44	18 SEP 2020 15:44
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

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: 12 Aug 2021 13:32:45

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

18 SEP 2020 17:05

PC Open Date & Time

18 SEP 2020 16:56

PC Close Date & Time

18 SEP 2020 19:26

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

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

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 18 SEP 2020 20:21

PC Close Date & Time 19 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 SEP 2020 19:49

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	20 SEP 2020 20:31
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**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

97.7 °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

21 SEP 2020 20:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**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

97.7 °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

22 SEP 2020 12:01

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

23 SEP 2020 20:12

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

**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

97.3 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

24 SEP 2020 20:06

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 12 Aug 2021 13:32:45

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**TIMEPOINT**

DAY 9

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

27 SEP 2020 06:25

---

PC Open Date & Time

26 SEP 2020 12:00

---

PC Close Date & Time

27 SEP 2020 11:59

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US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**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

18 SEP 2020 17:06

PC Open Date & Time

18 SEP 2020 16:56

PC Close Date & Time

18 SEP 2020 19:26

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**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

18 SEP 2020 20:21

PC Close Date & Time

19 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**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

19 SEP 2020 19:49

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**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

20 SEP 2020 20:32

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**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

21 SEP 2020 20:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**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

22 SEP 2020 12:01

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59



US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**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

23 SEP 2020 20:13

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

**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

24 SEP 2020 20:07

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**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 ☐

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 17:06
PC Open Date & Time	18 SEP 2020 16:56
PC Close Date & Time	18 SEP 2020 19:26

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**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 ☐

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 20:21

PC Close Date & Time

19 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:32:45

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 ☒

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 19:51
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59



US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:32:45

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)

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 20:32
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

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)

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 20:24
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:32:45

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)

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:02
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:32:45

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 20:14
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59



US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:32:45

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)

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US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 20:08
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:32:45

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 27 SEP 2020 06:26

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 12 Aug 2021 13:32:45

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**

None ☐

**ACHES IN SEVERAL JOINTS**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 12 Aug 2021 13:32:45

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**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 27 SEP 2020 06:26

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

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US3842040

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:32:45

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3842040

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:32:45

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 SEP 2020 06:26
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59



US3842040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:47:43

Generated On: 12 Aug 2021 13:32:45

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

Visit date (dd MMM yyyy)	16 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:47:44

Generated On: 12 Aug 2021 13:32:45

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)	16 OCT 2020
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 10:16
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG



US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:47:44

Generated On: 12 Aug 2021 13:32:45

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)	16 OCT 2020
Time of assessment (00:00-23:59)	12:54 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 12:54
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3842040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

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.*

US3842040

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 16 OCT 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3842040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

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) 16 OCT 2020

What was the treatment time? (00:00-23:59) 12:18 (24 HR)

Treatment Date and Time (derived) 16 OCT 2020 12:18

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

US3842040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

10:52 (24 HR)

Collection date and time (derived)

16 OCT 2020 10:52

US3842040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

Collection date (dd MMM yyyy)			16 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:55	16 OCT 2020 10:55
Nasopharyngeal Swab 2	No		

US3842040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 16 OCT 2020 12:58

PC Open Date & Time 16 OCT 2020 12:38

PC Close Date & Time 16 OCT 2020 15:08



US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**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 97.8 °F

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

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

PC Time Stamp	16 OCT 2020 18:54
PC Open Date & Time	16 OCT 2020 16:03
PC Close Date & Time	17 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 21:10

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

18 OCT 2020 17:05

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**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

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 OCT 2020 19:18

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

20 OCT 2020 17:41

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 OCT 2020 14:53

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

**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

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 OCT 2020 20:20

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 15:33

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59



US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**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

16 OCT 2020 12:58

PC Open Date & Time

16 OCT 2020 12:38

PC Close Date & Time

16 OCT 2020 15:08

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**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

16 OCT 2020 18:54

PC Open Date & Time

16 OCT 2020 16:03

PC Close Date & Time

17 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**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

17 OCT 2020 21:10

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**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

18 OCT 2020 17:05

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**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

19 OCT 2020 19:19

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**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

20 OCT 2020 17:41

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**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

21 OCT 2020 14:53

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

**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

22 OCT 2020 20:21

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59



US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**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 ☐

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 12:59
PC Open Date & Time	16 OCT 2020 12:38
PC Close Date & Time	16 OCT 2020 15:08

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**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 ☐

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 18:54
PC Open Date & Time	16 OCT 2020 16:03
PC Close Date & Time	17 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:32:45

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)

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 21:12
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:32:45

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)

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 17:05
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59



US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

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

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EAB) (1725)

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 19:19
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:32:45

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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US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 17:42
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:32:45

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)

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 14:54
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:32:45

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 ☒

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 20:21
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59



US3842040

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 23 OCT 2020 15:33

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 23 OCT 2020 15:33

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 OCT 2020 15:33

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 23 OCT 2020 15:33

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3842040

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:32:45

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 15:33
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3842040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

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



US3842040

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:47:43

Generated On: 12 Aug 2021 13:32:45

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3842040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

TIMEPOINT	DAY 68
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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 09:24:44
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59



US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 18:05:13

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 DEC 2020 18:00:45
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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 <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	13 DEC 2020 05:07:33
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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	20 DEC 2020 06:11:11
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 07:09:41

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

06 JAN 2021 21:26:42

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

10 JAN 2021 07:54:56

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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	17 JAN 2021 05:37:00
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59



US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

24 JAN 2021 06:24:36

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

03 FEB 2021 15:47:17

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

07 FEB 2021 11:43:10

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 FEB 2021 12:00:46
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

24 FEB 2021 23:54:56

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 10:57:54
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

08 MAR 2021 10:06:36

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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	14 MAR 2021 07:21:31
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59



US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 09:44:40

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 05:41:37

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

04 APR 2021 06:42:03

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

11 APR 2021 06:44:38

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

18 APR 2021 20:43:16

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

25 APR 2021 06:57:20

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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

02 MAY 2021 06:28:51

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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="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"/>



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 243

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

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 250

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

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

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

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

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 264

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

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

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

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

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

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 ☐



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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°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 ☐



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 341

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

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

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

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

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

Fever (Temperature  $\geq$  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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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09 SEP 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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 <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"/>

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 404

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

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

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

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

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

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



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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28 OCT 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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°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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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"/>



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

19 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59
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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 488

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

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

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

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

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

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



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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27 JAN 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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30 JAN 2022 00:01

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03 FEB 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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06 FEB 2022 00:01

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10 FEB 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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17 FEB 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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24 FEB 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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03 MAR 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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06 MAR 2022 00:01

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10 MAR 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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 ☐



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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13 MAR 2022 00:01

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17 MAR 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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20 MAR 2022 00:01

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24 MAR 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	03 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 APR 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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"/>



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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"/>

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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"/>



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 649

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

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

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

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

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

Fever (Temperature  $\geq$  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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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"/>



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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"/>



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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="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"/>



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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"/>



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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 <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"/>

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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16 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 768

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**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°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 ☐

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3842040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:45

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="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"/>



**US3842040**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

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

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

**US3842040**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 12 Aug 2021 13:32:45**

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
Yes	Yes	01 MAR 2021 10:57:40

US3842040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3842040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 17:12:37

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 17:12:37

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

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

Visit date (dd MMM yyyy)	16 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3842040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 APR 2021
Time of assessment (00:00-23:59)	10:23 (24 HR)
Vital Signs Date and Time (derived)	16 APR 2021 10:23
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3842040

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

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.*

US3842040

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 APR 2021

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

16 APR 2021 10:30

US3842040

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3842040**

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

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

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*



**US3842040**

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

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Date of Contact	03 NOV 2020
Time of Contact	11:00
Date and Time of Contact (derived)	03 NOV 2020 11:00
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" 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 checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	4 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.2 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	5 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	8 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	92 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.7 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 10:35:18

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Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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Form: Symptom Log (6)

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Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	3 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.5 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (7)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input checked="" type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input checked="" type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 10:35:18

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input checked="" type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input checked="" type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input checked="" type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input checked="" type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input checked="" type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input checked="" type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input checked="" type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.3 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input checked="" type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input checked="" type="radio"/>
	Day 34	<input type="radio"/>
	Day 35	<input type="radio"/>
	Day 36	<input type="radio"/>
	Day 37	<input type="radio"/>
	Day 38	<input type="radio"/>
	Day 39	<input type="radio"/>
	Day 40	<input type="radio"/>

Date	30 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input checked="" type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (31)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="radio"/>
	Day 34	<input type="radio"/>
	Day 35	<input type="radio"/>
	Day 36	<input checked="" type="radio"/>
	Day 37	<input type="radio"/>
	Day 38	<input type="radio"/>
	Day 39	<input type="radio"/>
	Day 40	<input type="radio"/>
Date	3 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (31)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (33)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (33)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (33)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (33)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (35)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (35)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	1 NOV 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (35)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (35)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	2 NOV 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (37)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (37)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Day 33	<input type="checkbox"/>
	Day 34	<input checked="" type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	1 DEC 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (37)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (37)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

Date of Visit 3 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Date of Test 3 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☒  
Nasal Swab ☐  
Saliva Test ☐  
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒  
No ☐

If yes, provide lab information below

Lab/ Institution Test Performed UNIVERSITY HOSPITAL NEW  
JERSEY MEDICAL SCHOOL  
CLINICAL RESEARCH CENTER

CLIA Certified? Yes ☒  
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 8 NOV 2020

End Date 10 NOV 2020

Oxygen Saturation 92 %

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

If Yes to either Did subject require any of the following:

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Mechanical Ventilation? Yes ☐  
No ☐

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

ECMO? Yes ☐  
No ☐

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐  
No ☒

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date \_\_\_\_\_

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date \_\_\_\_\_

PRODUCTION RELEASE (v12.003

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US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒  
No ☐

Date of Assessment 10 NOV 2020

Radiographical Evidence Yes ☒  
No ☐

Date of Assessment 09 NOV 2020

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Feb 2021 19:03:21

Generated On: 12 Aug 2021 13:32:45

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[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

---

US3842040

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Date of Contact	16 FEB 2021
Time of Contact	16:30
Date and Time of Contact (derived)	16 FEB 2021 16:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>



US3842040

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Date of Visit	17 FEB 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	17 FEB 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	UNIVERSITY HOSPITAL
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3842040

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Date of Contact	23 FEB 2021
Time of Contact	07:40
Date and Time of Contact (derived)	23 FEB 2021 07:40
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3842040

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 06 Mar 2021 00:06:53

Generated On: 12 Aug 2021 13:32:45

Date of Visit 23 FEB 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐  
No ☒

Date of Test 23 FEB 2021

Type of Test Performed Nasopharyngeal Swab ☒  
Nasal Swab ☐  
Saliva Test ☐  
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒  
No ☐

If yes, provide lab information below

Lab/ Institution Test Performed CLIA: 31D2184476/31D1085261

RUTGERS NJMS

CLIA Certified? Yes ☒  
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3842040

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	5 NOV 2020
Day 5	Yes	6 NOV 2020
Day 7	Yes	9 NOV 2020
Day 9	Yes	11 NOV 2020
Day 14	Yes	16 NOV 2020
Day 21	Yes	23 NOV 2020
Day 28	Yes	4 DEC 2020

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 26 Feb 2021 19:03:22

**Generated On: 12 Aug 2021 13:32:45**

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3842040

Folder: Illness Visit (3)

Form: Saliva Collection

Data signed: (b) (4) 26 Feb 2021 19:03:22

Generated On: 12 Aug 2021 13:32:45

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3842040

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:47:43

Generated On: 12 Aug 2021 13:32:45

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

Visit date (dd MMM yyyy)	3 NOV 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 NOV 2020
Time of assessment (00:00-23:59)	11:13 (24 HR)
Vital Signs Date and Time (derived)	3 NOV 2020 11:13
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3842040

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 NOV 2020

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

US3842040

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

3 NOV 2020

US3842040

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 19:03:23

Generated On: 12 Aug 2021 13:32:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 15:55:22

Generated On: 12 Aug 2021 13:32:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 FEB 2021
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 11:50
Height (xxx.x)	
Weight (xxx.x)	
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3842040

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 19:03:23

Generated On: 12 Aug 2021 13:32:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 FEB 2021

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

US3842040

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Feb 2021 19:03:22

Generated On: 12 Aug 2021 13:32:45

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

17 FEB 2021

US3842040

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 19:03:23

Generated On: 12 Aug 2021 13:32:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 15:55:22

Generated On: 12 Aug 2021 13:32:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	11:51 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 11:51
Height (xxx.x)	
Weight (xxx.x)	
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3842040

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 19:03:23

Generated On: 12 Aug 2021 13:32:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3842040

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Feb 2021 19:03:23

Generated On: 12 Aug 2021 13:32:45

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 FEB 2021

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:47:43

Generated On: 12 Aug 2021 13:32:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	4 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	09:59 (24 HR)
Vital Signs Date and Time (derived)	4 DEC 2020 09:59
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 DEC 2020

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

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

4 DEC 2020

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 19:03:21

Generated On: 12 Aug 2021 13:32:45

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

Visit date (dd MMM yyyy)

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

Folder OID	SICKD28
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US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_



US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 17:12:27

Generated On: 12 Aug 2021 13:32:45

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.*

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 30 Mar 2021 17:12:27

Generated On: 12 Aug 2021 13:32:45

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 19:03:21

Generated On: 12 Aug 2021 13:32:45

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

Visit date (dd MMM yyyy)

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

Folder OID	SICKD28
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US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 19:03:21

Generated On: 12 Aug 2021 13:32:45

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 19:03:20

Generated On: 12 Aug 2021 13:32:45

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.*

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Feb 2021 19:03:20

Generated On: 12 Aug 2021 13:32:45

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3842040

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:47:43

Generated On: 12 Aug 2021 13:32:45

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

Visit date (dd MMM yyyy)	13 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3842040

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:55:22

Generated On: 12 Aug 2021 13:32:45

Date of updated informed consent ( <i>dd MMM yyyy</i> )	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1



US3842040

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 18:47:44

Generated On: 12 Aug 2021 13:32:45

Height

Weight

BMI (xxx.x)

US3842040

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:47:44

Generated On: 12 Aug 2021 13:32:45

Height	
Weight	
BMI (xxx.x)	
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)	13 JAN 2021
Time of assessment (00:00-23:59)	11:51 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 11:51
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3842040

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:47:44

Generated On: 12 Aug 2021 13:32:45

Height	
Weight	
BMI (xxx.x)	
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)	13 JAN 2021
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 15:05
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3842040

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

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

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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.*

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US3842040

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

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	13 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3842040

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 13 JAN 2021

What was the treatment time? (00:00-23:59) 14:20 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 14:20

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

What was the frequency of the study treatment dosing? ONCE

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

US3842040

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

12:25 (24 HR)

Collection date and time (derived)

13 JAN 2021 12:25

US3842040

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

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)	12:28
Collection Date and Time (derived)	13 JAN 2021 12:28



US3842040

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3842040

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:47:43

Generated On: 12 Aug 2021 13:32:45

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

Visit date (dd MMM yyyy)	15 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:47:44

Generated On: 12 Aug 2021 13:32:45

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)	15 FEB 2021
Time of assessment (00:00-23:59)	12:01 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 12:01
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:47:44

Generated On: 12 Aug 2021 13:32:45

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)	15 FEB 2021
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 14:14
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3842040

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

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.*

US3842040

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 18:47:41

Generated On: 12 Aug 2021 13:32:45

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	15 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	



US3842040

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 15 FEB 2021

What was the treatment time? (00:00-23:59) 13:42 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 13:42

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

US3842040

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:06:53

Generated On: 12 Aug 2021 13:32:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842040

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:06:53

Generated On: 12 Aug 2021 13:32:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842040

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 15:55:22

Generated On: 12 Aug 2021 13:32:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3842040

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 15:55:22

Generated On: 12 Aug 2021 13:32:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	14:35 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 14:35
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	79 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3842040

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 15:55:22

Generated On: 12 Aug 2021 13:32:45

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.*

US3842040

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 15:55:22

Generated On: 12 Aug 2021 13:32:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 MAR 2021

Collection time (00:00-23:59)

15:00 (24 HR)

Collection date and time (derived)

22 MAR 2021 15:00



US3842040

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3842040

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID	USA-US110-2020-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	29 OCT 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)	4 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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	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	
MEDICATIONS LISTED IN CONCOMITANT MEDICATIONS LIST PER PROTOCOL	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID

Adverse event

PALPITATION

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)

01 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

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 (2)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID

Adverse event

VIRAL PNEUMONIA

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)

10 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

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 (3)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID

Adverse event

WORSENING INTERMITTENT  
HEART BURN

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)

14 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID	
Adverse event	VERTIGO
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	23 OCT 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)	24 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" 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)	

US3842040

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID

Adverse event

RIGHT EYE REDNESS

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 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

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 (6)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID	
Adverse event	CARDIAC MURMUR
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (7)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID	
Adverse event	TINNITUS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	24 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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 type="radio"/> Related <input checked="" 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 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID

Adverse event

FLU-LIKE SYMPTOMS: FOR AE #  
20.  
PLAN: WILL INACTIVATE AE 21,  
22, 23, 24, 25, 26, 27, 28, 29, 30, 31,  
AND 32 (UNLESS SOME OF  
THESE AE HAVE ALREADY  
BEEN DEACTIVATED) PER  
NARRATIVE BELOW

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)

16 FEB 2021

Start time (00:00-23:59)

12:30 (24 HR)

AE start date and time (derived)

16 FEB 2021 12:30

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 MAR 2021

End time (00:00-23:59)

10:00 (24 HR)

AE End Date and Time (derived)

08 MAR 2021 10:00

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)

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Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 30 Apr 2021 00:57:38

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Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/>
	No <input type="radio"/>
	Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/>
	Related <input checked="" 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 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	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	

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Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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PER QUERY, AE # 20, 21, 22, 23,  
24, 25, 26, 27, 28, 29, 30, 31 AND  
32 HAVE OVERLAPPING  
START/END DATES.  
PER QUERY REQUEST, THESE  
AE SYMPTOMS WILL BE  
COMBINED INTO ONE MEDICAL  
CONDITION OR DIAGNOSIS:  
FLU-LIKE SYMPTOMS. COVID  
NP COLLECTED ON 2/23/2021  
RESULTED NEGATIVE

---

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

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Folder: Adverse Events

Form: Adverse Events (34)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	9 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (34)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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	CONFIRMED COVID BY NP SWAB COLLECTED ON 11/03/2020 "NAUSEA" THIS AE WILL BE DEACTIVATED
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
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Folder: Adverse Events

Form: Adverse Events (34)

Data signed: (b) (4) 30 Apr 2021 00:57:38

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Folder: Adverse Events

Form: Adverse Events (36)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

AEID

Adverse event

BODY ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (36)

Data signed: (b) (4) 30 Apr 2021 00:57:38

Generated On: 12 Aug 2021 13:32:45

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 type="radio"/> Related <input checked="" 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

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

Yes ☒

No ☐

---

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

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US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication SYMBICORT

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

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 ☐  
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 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)		01 JAN 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)		_____
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 (2)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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 UNK 1986	
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) _____		
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 (3)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication OCCASIONAL TENSION  
HEADACHES

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1979	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 FEB 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 (4)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication NORVASC

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 MAR 2012	
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 10:35:17

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Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (5)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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 APR 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input 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 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication SINGULAR

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 (8)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication WIXELA

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 250/50

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 (9)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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 UNK 2019	
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) _____		
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 (10)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication ALLEGRA

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)	_____	
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 (11)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication ESOMEPRAZOLE (NEXIUM)

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

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 (11)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 (12)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication FLONASE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 200

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 (12)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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 2005	
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) _____		
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 (13)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication EUFLEXXA  
(SODIUM HYALURONATE  
INTRA-ARTICULAR INJECTION,  
1%)

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS BILATERAL  
KNEE'S

Dose per administration 10

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify TWICE A YEAR

Route of administration Oral ☐  
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 10:35:17

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	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input checked="" type="checkbox"/>
If route of administration is Other, specify	INJECT INTRA-ARTICULARLY	
Start date (dd MMM yyyy)	UN UNK 2011	
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)		
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 (14)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication BODY ACHES

Dose per administration 650

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 (14)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 OCT 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (15)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication TYLENOL ARTHRITIS

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 650

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)

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)	2 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
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 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication

NYQUIL: ACTIVE  
INGREDIENTS (IN EACH 30 ML  
DOSE CUP): ACETAMINOPHEN  
650 MG, DEXTROMETHORPHAN  
HBR 30 MG, DOXYLAMINE  
SUCCINATE 12.5 MG

Prophylaxis

Yes ☐

No ☒

Indication

NASAL CONGESTION

Dose per administration

30

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 ☒

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EAB) (1725)

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 NOV 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 (18)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication SYMBICORT

Prophylaxis Yes ☐  
No ☒

Indication SHORTNESS OF BREATH

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 ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)	7 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA

Dose per administration 8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)	9 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication TESSALON PERLES

Prophylaxis Yes ☐  
No ☒

Indication COUGH

Dose per administration 200

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 (20)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 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 (21)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 FEB 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 (22)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication COVID19

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

6 TABS ON 10NOV, 5 TABS ON  
11NOV, 4 TABS 12NOV, 3 TABS  
13NOV, 2 TABS 14NOV, 1 TAB  
15NOV

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 NOV 2020
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 (23)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication ALBUTEROL/PROAIR

Prophylaxis Yes ☐  
No ☒

Indication SHORTNESS OF BREATH

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
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 (24)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)	03 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 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 (27)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication PEPCID (FAMOTIDINE)

Prophylaxis Yes ☐  
No ☒

Indication HEARTBURN

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 (27)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 NOV 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 (28)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication OMEPRAZOLE (PRILOSEC)

Prophylaxis Yes ☐  
No ☒

Indication HEART BURN

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 (28)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication PREVACID (LANSOPRAZOLE)

Prophylaxis Yes ☐  
No ☒

Indication HEART BURN

Dose per administration 30

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)

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020	
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"/>

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication BODY ACHES, MUSCLE ACHES

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)		17 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication TYLENOL ARTHRITIS

Prophylaxis Yes ☐  
No ☒

Indication SORE THROAT, HEADACHE,  
CHILLS, BODY ACHES

Dose per administration 1300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 MAR 2021	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication BOTOX

Prophylaxis Yes ☐  
No ☒

Indication COSMETIC

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

EVERY 3 TO 4 MONTHS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRADERMALLY	
Start date (dd MMM yyyy)	UN 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 (35)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication

NYQUIL: ACTIVE  
INGREDIENTS (IN EACH 30 ML  
DOSE CUP): ACETAMINOPHEN  
650 MG, DEXTROMETHORPHAN  
HBR 30 MG, DOXYLAMINE  
SUCCINATE 12.5 MG

Prophylaxis

Yes ☐

No ☒

Indication

RUNNY NOSE

Dose per administration

30

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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 NOV 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 (36)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication SPIRIVA HANDIHALER  
(TIOTROPIUM BROMIDE)

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

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	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)	20 MAR 2021	
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 (37)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication ANTICOAGULANT (COVID)

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 10:35:17

Generated On: 12 Aug 2021 13:32:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 18:47:39

Generated On: 12 Aug 2021 13:32:45

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3842040

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

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

US3842040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 16 Feb 2021 18:47:40

Generated On: 12 Aug 2021 13:32:45

Date of study discontinuation/completion (*dd MMM yyyy*)

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 (*dd MMM yyyy*)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

SAEID	USA-US110-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	7

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

SAEID	USA-US110-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	7
Date of submission (Pre-filled from custom function)	05/NOV/2020 16:29
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

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

SAEID	USA-US110-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	7
Date of submission (Pre-filled from custom function)	01/DEC/2020 15:25
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



US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

SAEID	USA-US110-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	7
Date of submission (Pre-filled from custom function)	02/DEC/2020 08:15
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

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

SAEID	USA-US110-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	7
Date of submission (Pre-filled from custom function)	11/DEC/2020 09:01
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

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

SAEID	USA-US110-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	7
Date of submission (Pre-filled from custom function)	05/JAN/2021 20:14
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

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

SAEID	USA-US110-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	7
Date of submission (Pre-filled from custom function)	25/JAN/2021 20:44
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

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 10:35:18

Generated On: 12 Aug 2021 13:32:45

SAEID	USA-US110-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	7
Date of submission (Pre-filled from custom function)	01/APR/2021 16:23
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

US3842040 (Prod: New Jersey Medical School)

**US3842040**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:32:45**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:59:39
User entered 'US3842040'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 18:04:16

**US3842040**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:36:11
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:16:07



**US3842040**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:36:11
User entered '18 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 18:04:17

**US3842040**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:36:11
User entered 'Clinic (Clinic)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:16:07

**US3842040**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'SCRN'	System	18 Sep 2020 19:16:07

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered (b) (6) 1971'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 18:04:17

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered '49'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'YEARS'	System	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '49'	System	18 Sep 2020 19:16:38

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered 'Female (F)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13



**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered 'I'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13



**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:32:45**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:38:45
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:13

**US3842040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:44:30
User entered '18 Sep 2020'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:16:38

**US3842040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Sep 2020'	System	18 Sep 2020 19:16:38

**US3842040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '2020'	System	18 Sep 2020 19:16:38

**US3842040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:32:45**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:44:30
User entered 'Amendment 3 (3)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:16:38

**US3842040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:44:30
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:16:38

**US3842040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:44:30
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:16:38



**US3842040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:32:45**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:44:30
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:16:38

**US3842040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:32:45**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:44:30
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:16:38

**US3842040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:32:45**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:44:30
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 18:04:17

**US3842040**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:32:45**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'I'	System	18 Sep 2020 19:16:45

**US3842040**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:54:48
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:16:45

**US3842040**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 12 Aug 2021 13:32:45**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:55:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:37:09
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 22:11:00

US3842040

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:45

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:38:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:38:35
Data point term sent to Coder	System	23 Sep 2020 14:37:53
User entered 'hypertension'	(b) (4), (b) (6)	23 Sep 2020 14:37:36

**US3842040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'un UNK 2012'	(b) (4), (b) (6)	23 Sep 2020 14:37:36



**US3842040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:37:36

**US3842040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:37:36

**US3842040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:37:36

**US3842040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:37:36

**US3842040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 2012'	System	23 Sep 2020 14:37:36

**US3842040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '2012'	System	23 Sep 2020 14:37:36

**US3842040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:37:36

**US3842040**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:37:36



US3842040

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:45

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:40:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:40:25
Data point term sent to Coder	System	23 Sep 2020 14:38:54
User entered 'hypercholesterol'	(b) (4), (b) (6)	23 Sep 2020 14:38:05

**US3842040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'un UNK 2014'	(b) (4), (b) (6)	23 Sep 2020 14:38:05

US3842040

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:38:05

**US3842040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:38:05

**US3842040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:38:05

**US3842040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:38:05

**US3842040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 2014'	System	23 Sep 2020 14:38:05

**US3842040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '2014'	System	23 Sep 2020 14:38:05



**US3842040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:38:05

**US3842040**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:38:05

US3842040

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:32:45

[Condition](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:39:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:39:39
Data point term sent to Coder	System	23 Sep 2020 14:38:54
User entered 'latex allergy'	(b) (4), (b) (6)	23 Sep 2020 14:38:25

**US3842040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'un UNK 1995'	(b) (4), (b) (6)	23 Sep 2020 14:38:25

**US3842040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:38:25

**US3842040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:38:25

**US3842040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:38:25

**US3842040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:38:25



**US3842040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 1995'	System	23 Sep 2020 14:38:25

**US3842040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '1995'	System	23 Sep 2020 14:38:25

**US3842040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:38:25

**US3842040**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:38:25

US3842040

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:32:45

[Condition](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:39:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:39:40
Data point term sent to Coder	System	23 Sep 2020 14:38:55
User entered 'mango allergy'	(b) (4), (b) (6)	23 Sep 2020 14:38:45

**US3842040**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'un UNK 1998'	(b) (4), (b) (6)	23 Sep 2020 14:38:45

**US3842040**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:38:45

**US3842040**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:38:45



**US3842040**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:38:45

**US3842040**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:38:45

**US3842040**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 1998'	System	23 Sep 2020 14:38:45

**US3842040**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '1998'	System	23 Sep 2020 14:38:45

**US3842040**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:38:45

**US3842040**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:38:45

US3842040

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:32:45

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:40:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:40:43
Data point term sent to Coder	System	23 Sep 2020 14:39:55
User entered 'type 2 diabetes'	(b) (4), (b) (6)	23 Sep 2020 14:39:10

US3842040

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:32:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Malithi Desilva (b) (4)	06 Nov 2020 23:52:50
User entered 'UN UNK 2013' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	06 Nov 2020 23:52:50
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'un UNK 2015'	(b) (4), (b) (6)	23 Sep 2020 14:39:10



**US3842040**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:39:10

**US3842040**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:39:10

**US3842040**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:39:10

**US3842040**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:39:10

**US3842040**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 2013'	System	06 Nov 2020 23:52:50
User entered 'Jan 2015'	System	23 Sep 2020 14:39:10

**US3842040**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '2013'	System	06 Nov 2020 23:52:50
User entered '2015'	System	23 Sep 2020 14:39:10

**US3842040**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:39:10

**US3842040**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:39:10



US3842040

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:32:45

[Condition](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
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 Sep 2020 14:40:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:40:42
Data point term sent to Coder	System	23 Sep 2020 14:39:55
User entered 'asthma (moderate)'	(b) (4), (b) (6)	23 Sep 2020 14:39:32

US3842040

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:32:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Malithi Desilva (b) (4)	06 Nov 2020 23:40:45
User entered 'UN UNK 1986' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	06 Nov 2020 23:40:45
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'un UNK 2015'	(b) (4), (b) (6)	23 Sep 2020 14:39:32

**US3842040**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:39:32

**US3842040**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:39:32

**US3842040**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:39:32

**US3842040**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:39:32

**US3842040**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 1986'	System	06 Nov 2020 23:40:45
User entered 'Jan 2015'	System	23 Sep 2020 14:39:32

**US3842040**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '1986'	System	06 Nov 2020 23:40:45
User entered '2015'	System	23 Sep 2020 14:39:32



**US3842040**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:39:32

**US3842040**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	23 Sep 2020 14:39:32

US3842040

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:32:45

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:06:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:06:12
Data point term sent to Coder	System	15 Oct 2020 15:32:06
User entered 'Acid Reflux'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:33

**US3842040**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'UN UNK 2019'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:33

US3842040

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:32:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:33

US3842040

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:32:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:33

US3842040

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:33

US3842040

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:32:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:33



**US3842040**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 2019'	System	15 Oct 2020 15:31:33

**US3842040**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '2019'	System	15 Oct 2020 15:31:33

**US3842040**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	15 Oct 2020 15:31:33

**US3842040**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	15 Oct 2020 15:31:33

US3842040

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:32:45

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:06:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:06:07
Data point term sent to Coder	System	15 Oct 2020 15:32:06
User entered 'Seasonal Allergies'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:59

**US3842040**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'UN UNK 2005'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:59

**US3842040**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:59

**US3842040**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:59



**US3842040**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:59

US3842040

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:32:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:31:59

**US3842040**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 2005'	System	15 Oct 2020 15:31:59

**US3842040**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '2005'	System	15 Oct 2020 15:31:59

**US3842040**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	15 Oct 2020 15:31:59

**US3842040**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	15 Oct 2020 15:31:59

US3842040

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:32:45

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Tension headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:06:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:06:13
Data point term sent to Coder	System	15 Oct 2020 15:33:07
User entered 'Occasional Tension Headache'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:32:34

**US3842040**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'UN UNK 1979'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:32:34



**US3842040**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:32:34

**US3842040**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:32:34

US3842040

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:32:34

**US3842040**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:08
User entered '0'	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:32:34

**US3842040**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 1979'	System	15 Oct 2020 15:32:34

**US3842040**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '1979'	System	15 Oct 2020 15:32:34

**US3842040**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	15 Oct 2020 15:32:34

**US3842040**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	15 Oct 2020 15:32:34



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Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:32:45

[Condition](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 20:39:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 20:39:41
Data point term sent to Coder	System	15 Feb 2021 20:38:54
Coding entries removed.	Zoraida Cruz (b) (4)	15 Feb 2021 20:38:12
User entered 'Bilateral Osteoarthritis' reason for change: New Information	Zoraida Cruz (b) (4)	15 Feb 2021 20:38:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 18:40:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 18:40:51
Data point term sent to Coder	System	01 Dec 2020 18:40:08
User entered 'Osteoarthritis, Right knee'	Malithi Desilva (b) (4)	01 Dec 2020 18:39:18

**US3842040**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'UN UNK 2010'	(b) (4) Malithi Desilva (b) (4) (b) (4)	01 Dec 2020 18:39:18

**US3842040**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	01 Dec 2020 18:39:18

**US3842040**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	01 Dec 2020 18:39:18

**US3842040**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	01 Dec 2020 18:39:18

US3842040

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:32:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	01 Dec 2020 18:39:18

**US3842040**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 2010'	System	01 Dec 2020 18:39:18

**US3842040**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '2010'	System	01 Dec 2020 18:39:18



**US3842040**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	01 Dec 2020 18:39:18

**US3842040**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	01 Dec 2020 18:39:18

US3842040

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:32:45

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User coded data point as SOC: Eye disorders, HLGT: Ocular neuromuscular disorders, HLT: Eyelid movement disorders, PT: Blepharospasm, LLT: Blepharospasm - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Mar 2021 22:32:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 22:32:06
Data point term sent to Coder	System	01 Mar 2021 22:16:29
User entered 'blepharospasm'	Zoraida Cruz (b) (4) (b) (4)	01 Mar 2021 22:15:35

**US3842040**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'un UNK 2015'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	01 Mar 2021 22:15:35

**US3842040**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	01 Mar 2021 22:15:35

**US3842040**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'No (N)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	01 Mar 2021 22:15:35

**US3842040**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'un UNK 2015'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	01 Mar 2021 22:15:35

**US3842040**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	01 Mar 2021 22:15:35



**US3842040**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 2015'	System	01 Mar 2021 22:15:35

**US3842040**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '2015'	System	01 Mar 2021 22:15:35

US3842040

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'Jan 2015'	System	01 Mar 2021 22:15:35

**US3842040**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '2015'	System	01 Mar 2021 22:15:35

**US3842040**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53



**US3842040**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:49:17
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:00
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 09:46:08
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:07:48

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '18 Sep 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:07:48



US3842040

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User closed query 'please review time of assessment entry as source data states a time of 14:40 please review and update accordingly.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	26 Mar 2021 20:46:42
	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
Query 'please review time of assessment entry as source data states a time of 14:40 please review and update accordingly.' answered with 'vitals signs are directly entered into EPIC, the time stamp of vital sign entry is then recorded onto source document. DAIDS error corrected document to match EPIC ' (Site from CRA).	Malithi Desilva (b) (4)	06 Nov 2020 23:27:25
	(b) (4)	
User opened query 'please review time of assessment entry as source data states a time of 14:40 please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 17:06:14
User entered '14:42'	Malithi Desilva (b) (4)	18 Sep 2020 21:07:48
	(b) (4)	

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '18 Sep 2020 14:42'	System	18 Sep 2020 21:07:48

US3842040

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '158' cm	(b) (4) Malithi Desilva (b) (4)	18 Sep 2020 21:07:48
DataPoint set to visible.	(b) (4) System	18 Sep 2020 19:16:45

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '81' kg	(b) (4) Malithi Desilva (b) (4)	18 Sep 2020 21:07:48
DataPoint set to visible.	(b) (4) System	18 Sep 2020 19:16:45

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered '32.44672'	System	18 Sep 2020 21:07:48
DataPoint set to visible.	System	18 Sep 2020 19:16:45

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'kg/m2'	System	18 Sep 2020 21:07:48
DataPoint set to visible.	System	18 Sep 2020 19:16:45

US3842040

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:23
User entered '98.4' F	Christie Lyn Costanza	18 Sep 2020 21:07:48
	(b) (4)	

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:23
User entered 'Oral (Oral)'	Christie Lyn Costanza	18 Sep 2020 21:07:48
	(b) (4)	
	Malithi Desilva (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:07:48

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:23
User entered '80'	Christie Lyn Costanza	18 Sep 2020 21:07:48
	(b) (4)	
	Malithi Desilva	
	(b) (4)	
	(b) (4)	

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'bpm'	System	18 Sep 2020 21:07:48

US3842040

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:23
User entered '16'	Christie Lyn Costanza	18 Sep 2020 21:07:48
	(b) (4)	
	Malithi Desilva	
	(b) (4)	
	(b) (4)	

US3842040

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'breaths/min'	System	18 Sep 2020 21:07:48

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:23
User entered '123'	Christie Lyn Costanza	18 Sep 2020 21:07:48
	(b) (4)	
	Malithi Desilva	
	(b) (4)	
	(b) (4)	

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'mmHg'	System	18 Sep 2020 21:07:48

US3842040

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:23
User entered '72'	Christie Lyn Costanza	18 Sep 2020 21:07:48
	(b) (4)	
	Malithi Desilva	
	(b) (4)	
	(b) (4)	



**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered 'mmHg'	System	18 Sep 2020 21:07:48

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53

**US3842040**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:08:54
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:25

**US3842040**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:08:54
User entered '18 Sep 2020'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:17:25

**US3842040**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:32:45**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:09:08
User entered '18 Sep 2020'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:37

**US3842040**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:09:08
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:37

**US3842040**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:32:45**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:09:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:37



**US3842040**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:32:45**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:09:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:37

**US3842040**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:32:45**

*If Surgically sterile, date of surgery (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:09:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:37

**US3842040**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:32:45**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:09:08
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:37

**US3842040**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:32:45**

*If Post-menopausal, date of last menstruation (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:09:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:37

**US3842040**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:32:45**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:09:08
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:37

**US3842040**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:14:42
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:02:42

**US3842040**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:14:42
User entered '18 Sep 2020'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:02:42

**US3842040**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:14:42
User entered 'Urine (URINE)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:02:42



**US3842040**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:14:42
User entered 'Negative (NEGATIVE)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:02:42

US3842040

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:14:42
User closed query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:38:15
Query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' answered with 'corrected' (Site from DM).	Christie Lyn Costanza (b) (4)	06 Oct 2020 15:42:08
Query 'Per CDM: Please confirm if FSH test was administered and update as appropriate, else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:34:58
User opened query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:34:48
User opened query 'Per CDM: Please confirm if FSH test was administered and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 06:08:31
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	18 Sep 2020 22:09:52
User entered empty.	Malithi Desilva (b) (4)	18 Sep 2020 21:02:42

**US3842040**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:14:42
User entered empty; reason for change Data Entry Error	Christie Lyn Costanza	06 Oct 2020 15:42:04
User entered '18 Sep 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:02:42

**US3842040**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:14:42
User entered empty; reason for change Data Entry Error	Christie Lyn Costanza (b) (4)	06 Oct 2020 15:42:04
User entered '14:07' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 22:09:52
User entered '14:08'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:02:42

**US3842040**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User entered empty.	System	06 Oct 2020 15:42:04
User entered '18 Sep 2020 14:07'	System	18 Sep 2020 22:09:52
User entered '18 Sep 2020 14:08'	System	18 Sep 2020 21:02:42

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

**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 19:19:53
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:25:01
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 19:24:32
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

**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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

**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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12



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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

**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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

[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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

[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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

**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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

**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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

[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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

**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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

**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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12



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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 12 Aug 2021 13:32:45**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

**US3842040**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 12 Aug 2021 13:32:45**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

**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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

[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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

**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 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

US3842040

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:45

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered 'I'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12



**US3842040**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 12 Aug 2021 13:32:45**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

**US3842040**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:19:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:17:38
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:12

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:21

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '18 Sep 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:21

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Clinic (Clinic)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:21

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'VISIT1'	System	18 Sep 2020 19:19:21

US3842040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '18 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 19:04:42

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:32:45**

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '146269'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 19:04:42



**US3842040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:32:45**

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 19:04:42

US3842040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:45

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)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:39:56
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:06

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:32:45**

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)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:06

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:32:45**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:06

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:32:45**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:06

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:32:45**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:19:06

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:32:45**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:29:42
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:32:07
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:32:05

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:32:45**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:52
User entered '158' cm	Christie Lyn Costanza (b) (4)	18 Sep 2020 21:06:29
	(b) (4)	



US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:52
User entered '81' kg	Christie Lyn Costanza	18 Sep 2020 21:06:29
	(b) (4)	
	Malithi Desilva	
	(b) (4)	
	(b) (4)	

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:32:45**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:52
User entered '158' cm	Christie Lyn Costanza	18 Sep 2020 21:06:29
	(b) (4)	
	Malithi Desilva	
	(b) (4)	

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:52
User entered '81' kg	Christie Lyn Costanza (b) (4)	18 Sep 2020 21:06:29
	(b) (4)	

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User accepted default value 'Pre-Dose (PREDOSE)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '18 Sep 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '14:42'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '18 Sep 2020 14:42'	System	18 Sep 2020 21:06:29



**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.4' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Oral (Oral)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '80'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'bpm'	System	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '16'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'breaths/min'	System	18 Sep 2020 21:06:29

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '123'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'mmHg'	System	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '72'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'mmHg'	System	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:32:45**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:52
User entered '158' cm	Christie Lyn Costanza	18 Sep 2020 21:06:29
	(b) (4)	
	Malithi Desilva	
	(b) (4)	
	(b) (4)	

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 14:43:52
User entered '81' kg	Christie Lyn Costanza (b) (4)	18 Sep 2020 21:06:29
	(b) (4)	

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User accepted default value 'Post-Dose (POSTDOSE)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 14:22:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 14:22:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:22:08
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:06:29
User entered empty.	Malithi Desilva (b) (4)	18 Sep 2020 21:06:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:22:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 14:29:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 14:29:28
User entered '17:07' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:29:28
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 14:22:08
User entered empty.	Malithi Desilva (b) (4)	18 Sep 2020 21:06:29
	(b) (4)	

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '18 Sep 2020 17:07'	System	23 Sep 2020 14:29:28
User entered empty.	System	18 Sep 2020 21:06:29

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.1' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:22:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:22:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '72' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:22:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'bpm'	System	23 Sep 2020 14:22:08
User entered empty.	System	18 Sep 2020 21:06:29

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:22:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29



**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'breaths/min'	System	23 Sep 2020 14:22:08
User entered empty.	System	18 Sep 2020 21:06:29

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '131' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:22:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'mmHg'	System	23 Sep 2020 14:22:08
User entered empty.	System	18 Sep 2020 21:06:29

US3842040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '75' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:22:08
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:06:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'mmHg'	System	23 Sep 2020 14:22:08
User entered empty.	System	18 Sep 2020 21:06:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:18:31

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '18 Sep 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 19:18:31

US3842040

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1 and make rest other data points at this page as blank to avoid duplication of data. If a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:57:06
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1 and make rest other data points at this page as blank to avoid duplication of data. If a second test was not performed. Alternatively, please explain.' answered with 'corrected' (Site from DM).	Christie Lyn Costanza (b) (4)	06 Oct 2020 20:34:58
User entered 'No (N)' reason for change: Data Entry Error	Christie Lyn Costanza (b) (4)	06 Oct 2020 20:34:52
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1 and make rest other data points at this page as blank to avoid duplication of data. If a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 07:28:57
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 22:09:29



**US3842040**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty; reason for change Data Entry Error	(b) (4)	06 Oct 2020 20:34:52
User entered '18 Sep 2020'	Christie Lyn Costanza	06 Oct 2020 20:34:52
	(b) (4)	
	Malithi Desilva	18 Sep 2020 22:09:29
	(b) (4)	

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty; reason for change Data Entry Error	(b) (4)	06 Oct 2020 20:34:52
User entered 'Urine (URINE)'	Christie Lyn Costanza	06 Oct 2020 20:34:52
	(b) (4)	
	Malithi Desilva	18 Sep 2020 22:09:29
	(b) (4)	

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty; reason for change Data Entry Error	(b) (4)	06 Oct 2020 20:34:52
User entered 'Negative (NEGATIVE)'	Christie Lyn Costanza	06 Oct 2020 20:34:52
	(b) (4)	
	Malithi Desilva	18 Sep 2020 22:09:29
	(b) (4)	

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty; reason for change Data Entry Error	(b) (4)	06 Oct 2020 20:34:52
User entered 'No (N)'	Christie Lyn Costanza	06 Oct 2020 20:34:52
	(b) (4)	
	Malithi Desilva	18 Sep 2020 22:09:29
	(b) (4)	

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty; reason for change Data Entry Error	(b) (4)	06 Oct 2020 15:42:37
User entered '18 Sep 2020'	Christie Lyn Costanza	06 Oct 2020 15:42:37
	(b) (4)	
	Malithi Desilva	18 Sep 2020 22:09:29
	(b) (4)	

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty; reason for change Data Entry Error	(b) (4)	06 Oct 2020 15:42:37
User entered '14:07'	Christie Lyn Costanza	06 Oct 2020 15:42:37
	(b) (4)	
	Malithi Desilva	18 Sep 2020 22:09:29
	(b) (4)	

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered empty.	System	06 Oct 2020 15:42:37
User entered '18 Sep 2020 14:07'	System	18 Sep 2020 22:09:29

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:53



**US3842040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:53

US3842040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

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)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:53

US3842040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 21:03:53

US3842040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '18 Sep 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:53

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '16:36'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:53

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '18 Sep 2020 16:36'	System	18 Sep 2020 21:03:53

US3842040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 21:03:53

US3842040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'ONCE'	System	18 Sep 2020 21:03:53



US3842040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:30:05

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:30:05

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '15:40'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:30:05

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '18 Sep 2020 15:40'	System	23 Sep 2020 14:30:05

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 12 Aug 2021 13:32:45**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:30:22

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	23 Sep 2020 14:30:22

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:30:22



**US3842040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '15:44'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:30:22

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '18 Sep 2020 15:44'	System	23 Sep 2020 14:30:22

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	23 Sep 2020 14:30:22

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:30:22

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:32:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:30:22

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered empty.	System	23 Sep 2020 14:30:22

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:30:26

**US3842040**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'I'	System	23 Sep 2020 14:30:26



US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:05:21', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '316c85eb-9cc7-45f4-a09e-347e763767f4' User entered 'Yes (Y)'	System	18 Sep 2020 21:05:51
	System	18 Sep 2020 21:05:51

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:05:27', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '316c85eb-9cc7-45f4-a09e-347e763767f4' User entered '98.4'	System	18 Sep 2020 21:05:51
	System	18 Sep 2020 21:05:51

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:05:32', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '316c85eb-9cc7-45f4-a09e-347e763767f4' User entered 'No (N)'	System	18 Sep 2020 21:05:51
	System	18 Sep 2020 21:05:51

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:05:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '316c85eb-9cc7-45f4-a09e-347e763767f4' User entered '18 Sep 2020 17:05'	System	18 Sep 2020 21:05:51
	System	18 Sep 2020 21:05:51

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Sep 2020 16:56'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Sep 2020 19:26'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:03:53



US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Sep 2020 20:21'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:03:53



US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 2'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:48:41', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '13c0f49d-ecef-4fe2-b5c4-a84755f4d33c' User entered 'Yes (Y)'	System	19 Sep 2020 23:49:13
	System	19 Sep 2020 23:49:13

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:48:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '13c0f49d-ecef-4fe2-b5c4-a84755f4d33c' User entered '97.7'	System	19 Sep 2020 23:49:13
	System	19 Sep 2020 23:49:13

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:48:55', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '13c0f49d-ecef-4fe2-b5c4-a84755f4d33c'	System	19 Sep 2020 23:49:13
User entered 'Yes (Y)'	System	19 Sep 2020 23:49:13

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 09:41:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:49:01', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '13c0f49d-ecef-4fe2-b5c4-a84755f4d33c' User entered '1'	Christie Lyn Costanza (b) (4)	29 Sep 2020 00:56:08
	System	19 Sep 2020 23:49:13
	System	19 Sep 2020 23:49:13
	System	19 Sep 2020 23:49:13

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:49:01', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '13c0f49d-ecef-4fe2-b5c4-a84755f4d33c' User entered '0'	System	19 Sep 2020 23:49:13
	System	19 Sep 2020 23:49:13

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:49:10', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '13c0f49d-ecef-4fe2-b5c4-a84755f4d33c' User entered '19 Sep 2020 19:49'	System	19 Sep 2020 23:49:13
	System	19 Sep 2020 23:49:13

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:03:53



US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 3'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:31:22', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '91bc5a82-339e-4068-942b-2d5e1f518b4b' User entered 'Yes (Y)'	System	21 Sep 2020 00:31:53
	System	21 Sep 2020 00:31:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:31:30', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '91bc5a82-339e-4068-942b-2d5e1f518b4b' User entered '97.7'	System	21 Sep 2020 00:31:53
	System	21 Sep 2020 00:31:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:31:35', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '91bc5a82-339e-4068-942b-2d5e1f518b4b' User entered 'Yes (Y)'	System	21 Sep 2020 00:31:53
	System	21 Sep 2020 00:31:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 09:41:31
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:31:41', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '91bc5a82-339e-4068-942b-2d5e1f518b4b' User entered '1'	Christie Lyn Costanza (b) (4)	29 Sep 2020 00:56:18
	System	21 Sep 2020 00:31:53
	System	21 Sep 2020 00:31:53
	System	21 Sep 2020 00:31:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:31:41', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '91bc5a82-339e-4068-942b-2d5e1f518b4b' User entered '0'	System	21 Sep 2020 00:31:53
	System	21 Sep 2020 00:31:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:31:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '91bc5a82-339e-4068-942b-2d5e1f518b4b' User entered '20 Sep 2020 20:31'	System	21 Sep 2020 00:31:53
	System	21 Sep 2020 00:31:53



US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 4'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:23:50', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5947d798-c210-48c2-92da-89f8f8a034b2' User entered 'Yes (Y)'	System	22 Sep 2020 00:24:07
	System	22 Sep 2020 00:24:07

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:23:57', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5947d798-c210-48c2-92da-89f8f8a034b2' User entered '97.7'	System	22 Sep 2020 00:24:07
	System	22 Sep 2020 00:24:07

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5947d798-c210-48c2-92da-89f8f8a034b2'	System	22 Sep 2020 00:24:07
User entered 'No (N)'	System	22 Sep 2020 00:24:07

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:04', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5947d798-c210-48c2-92da-89f8f8a034b2'	System	22 Sep 2020 00:24:07
User entered '21 Sep 2020 20:24'	System	22 Sep 2020 00:24:07

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:03:53



US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 5'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:10', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd46d27f5-d430-4ac4-9716-4feeb84cef03' User entered 'Yes (Y)'	System	22 Sep 2020 16:02:20
	System	22 Sep 2020 16:02:20

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:14', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd46d27f5-d430-4ac4-9716-4feeb84cef03' User entered '97.7'	System	22 Sep 2020 16:02:20
	System	22 Sep 2020 16:02:20

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:17', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd46d27f5-d430-4ac4-9716-4feeb84cef03'	System	22 Sep 2020 16:02:20
User entered 'No (N)'	System	22 Sep 2020 16:02:20

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:20', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd46d27f5-d430-4ac4-9716-4feeb84cef03' User entered '22 Sep 2020 12:01'	System	22 Sep 2020 16:02:20
	System	22 Sep 2020 16:02:20

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:03:53



US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 6'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:12:21', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6b26bf8d-9018-46a6-bfe0-3c3116d06174' User entered 'Yes (Y)'	System	24 Sep 2020 00:13:01
	System	24 Sep 2020 00:13:01

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:12:39', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6b26bf8d-9018-46a6-bfe0-3c3116d06174' User entered '97.7'	System	24 Sep 2020 00:13:01
	System	24 Sep 2020 00:13:01

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:12:46', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6b26bf8d-9018-46a6-bfe0-3c3116d06174'	System	24 Sep 2020 00:13:01
User entered 'Yes (Y)'	System	24 Sep 2020 00:13:01

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 09:41:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:12:52', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6b26bf8d-9018-46a6-bfe0-3c3116d06174' User entered '1'	Christie Lyn Costanza (b) (4)	29 Sep 2020 00:56:29
	System	24 Sep 2020 00:13:01
	System	24 Sep 2020 00:13:01
	System	24 Sep 2020 00:13:01

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:12:52', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6b26bf8d-9018-46a6-bfe0-3c3116d06174' User entered '0'	System	24 Sep 2020 00:13:01
	System	24 Sep 2020 00:13:01

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:12:59', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6b26bf8d-9018-46a6-bfe0-3c3116d06174' User entered '23 Sep 2020 20:12'	System	24 Sep 2020 00:13:01
	System	24 Sep 2020 00:13:01

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:03:53



US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 7'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:06:43', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0398c133-0f6a-48cc-8749-b0b7384331dc' User entered 'Yes (Y)'	System	25 Sep 2020 00:07:03
	System	25 Sep 2020 00:07:03

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:06:47', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0398c133-0f6a-48cc-8749-b0b7384331dc' User entered '97.3'	System	25 Sep 2020 00:07:03
	System	25 Sep 2020 00:07:03

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:06:50', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0398c133-0f6a-48cc-8749-b0b7384331dc' User entered 'Yes (Y)'	System	25 Sep 2020 00:07:03
	System	25 Sep 2020 00:07:03

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 09:41:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:06:54', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0398c133-0f6a-48cc-8749-b0b7384331dc' User entered '1'	Christie Lyn Costanza (b) (4)	29 Sep 2020 00:56:58
	System	25 Sep 2020 00:07:03
	System	25 Sep 2020 00:07:03
	System	25 Sep 2020 00:07:03

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:06:54', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0398c133-0f6a-48cc-8749-b0b7384331dc' User entered '0'	System	25 Sep 2020 00:07:03
	System	25 Sep 2020 00:07:03

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:06:58', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0398c133-0f6a-48cc-8749-b0b7384331dc' User entered '24 Sep 2020 20:06'	System	25 Sep 2020 00:07:03
	System	25 Sep 2020 00:07:03



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	24 Sep 2020 00:13:01
User entered 'Day 8'	System	24 Sep 2020 00:13:01

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05



US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 00:13:01

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 00:13:01

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	25 Sep 2020 00:07:03
User entered 'Day 9'	System	25 Sep 2020 00:07:03

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-27T06:25:42', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '39dd2b67-45bd-4df9-a50f-86e949208faa' User entered 'Yes (Y)'	System	27 Sep 2020 10:25:59
	System	27 Sep 2020 10:25:59

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-27T06:25:48', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '39dd2b67-45bd-4df9-a50f-86e949208faa' User entered '97.3'	System	27 Sep 2020 10:25:59
	System	27 Sep 2020 10:25:59

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-27T06:25:50', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '39dd2b67-45bd-4df9-a50f-86e949208faa'	System	27 Sep 2020 10:25:59
User entered 'No (N)'	System	27 Sep 2020 10:25:59

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-27T06:25:54', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '39dd2b67-45bd-4df9-a50f-86e949208faa' User entered '27 Sep 2020 06:25'	System	27 Sep 2020 10:25:59
	System	27 Sep 2020 10:25:59



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 00:07:03

US3842040

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 00:07:03

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:10', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6626ac73-312f-4959-89b1-8413ad1598df' User entered 'None (1)'	System	18 Sep 2020 21:06:39
	System	18 Sep 2020 21:06:39

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:14', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6626ac73-312f-4959-89b1-8413ad1598df' User entered 'No (N)'	System	18 Sep 2020 21:06:39
	System	18 Sep 2020 21:06:39

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:17', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6626ac73-312f-4959-89b1-8413ad1598df' User entered 'No (N)'	System	18 Sep 2020 21:06:39
	System	18 Sep 2020 21:06:39

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:21', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6626ac73-312f-4959-89b1-8413ad1598df'	System	18 Sep 2020 21:06:39
User entered 'None (1)'	System	18 Sep 2020 21:06:39

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:25', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6626ac73-312f-4959-89b1-8413ad1598df' User entered '18 Sep 2020 17:06'	System	18 Sep 2020 21:06:39
	System	18 Sep 2020 21:06:39



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Sep 2020 16:56'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Sep 2020 19:26'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05



US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Sep 2020 20:21'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 2'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:49:23', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '870373e7-d69c-4389-b2c6-857ec506d962'	System	19 Sep 2020 23:49:44
User entered 'None (1)'	System	19 Sep 2020 23:49:44

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:49:26', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '870373e7-d69c-4389-b2c6-857ec506d962'	System	19 Sep 2020 23:49:44
User entered 'No (N)'	System	19 Sep 2020 23:49:44

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:49:29', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '870373e7-d69c-4389-b2c6-857ec506d962'	System	19 Sep 2020 23:49:44
User entered 'No (N)'	System	19 Sep 2020 23:49:44



US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:49:38', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '870373e7-d69c-4389-b2c6-857ec506d962'	System	19 Sep 2020 23:49:44
User entered 'None (1)'	System	19 Sep 2020 23:49:44

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:49:42', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '870373e7-d69c-4389-b2c6-857ec506d962' User entered '19 Sep 2020 19:49'	System	19 Sep 2020 23:49:44
	System	19 Sep 2020 23:49:44

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 3'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:31:56', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '062d821f-be2f-4277-a4fe-7fe608403677'	System	21 Sep 2020 00:32:20
User entered 'None (1)'	System	21 Sep 2020 00:32:20

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '062d821f-be2f-4277-a4fe-7fe608403677'	System	21 Sep 2020 00:32:20
User entered 'No (N)'	System	21 Sep 2020 00:32:20

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:03', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '062d821f-be2f-4277-a4fe-7fe608403677'	System	21 Sep 2020 00:32:20
User entered 'No (N)'	System	21 Sep 2020 00:32:20



US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:13', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '062d821f-be2f-4277-a4fe-7fe608403677'	System	21 Sep 2020 00:32:20
User entered 'None (1)'	System	21 Sep 2020 00:32:20

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:17', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '062d821f-be2f-4277-a4fe-7fe608403677'	System	21 Sep 2020 00:32:20
User entered '20 Sep 2020 20:32'	System	21 Sep 2020 00:32:20

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 4'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:09', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0bca0b66-ac66-4070-8d4b-70bfa8dbaba2'	System	22 Sep 2020 00:24:32
User entered 'None (1)'	System	22 Sep 2020 00:24:32

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:12', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0bca0b66-ac66-4070-8d4b-70bfa8dbaba2' User entered 'No (N)'	System	22 Sep 2020 00:24:32
	System	22 Sep 2020 00:24:32

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:14', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0bca0b66-ac66-4070-8d4b-70bfa8dbaba2' User entered 'No (N)'	System	22 Sep 2020 00:24:32
	System	22 Sep 2020 00:24:32



US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:22', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0bca0b66-ac66-4070-8d4b-70bfa8dbaba2'	System	22 Sep 2020 00:24:32
User entered 'None (1)'	System	22 Sep 2020 00:24:32

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:28', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0bca0b66-ac66-4070-8d4b-70bfa8dbaba2' User entered '21 Sep 2020 20:24'	System	22 Sep 2020 00:24:32
	System	22 Sep 2020 00:24:32

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 5'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:24', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '32edd0dd-8873-467a-a354-e5f86a79f47a' User entered 'None (1)'	System	22 Sep 2020 16:02:53
	System	22 Sep 2020 16:02:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:26', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '32edd0dd-8873-467a-a354-e5f86a79f47a' User entered 'No (N)'	System	22 Sep 2020 16:02:53
	System	22 Sep 2020 16:02:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:28', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '32edd0dd-8873-467a-a354-e5f86a79f47a' User entered 'No (N)'	System	22 Sep 2020 16:02:53
	System	22 Sep 2020 16:02:53



US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:38', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '32edd0dd-8873-467a-a354-e5f86a79f47a' User entered 'None (1)'	System	22 Sep 2020 16:02:53
	System	22 Sep 2020 16:02:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:44', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '32edd0dd-8873-467a-a354-e5f86a79f47a' User entered '22 Sep 2020 12:01'	System	22 Sep 2020 16:02:53
	System	22 Sep 2020 16:02:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 6'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:13:19', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f99711ff-92b7-4fcc-b95c-72c8b21248e8' User entered 'None (1)'	System	24 Sep 2020 00:13:58
	System	24 Sep 2020 00:13:58

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:13:22', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f99711ff-92b7-4fcc-b95c-72c8b21248e8' User entered 'No (N)'	System	24 Sep 2020 00:13:58
	System	24 Sep 2020 00:13:58

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:13:37', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f99711ff-92b7-4fcc-b95c-72c8b21248e8' User entered 'No (N)'	System	24 Sep 2020 00:13:58
	System	24 Sep 2020 00:13:58



US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:13:48', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f99711ff-92b7-4fcc-b95c-72c8b21248e8' User entered 'None (1)'	System	24 Sep 2020 00:13:58
	System	24 Sep 2020 00:13:58

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:13:53', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f99711ff-92b7-4fcc-b95c-72c8b21248e8' User entered '23 Sep 2020 20:13'	System	24 Sep 2020 00:13:58
	System	24 Sep 2020 00:13:58

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 7'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:07:03', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '53ec3aca-c2fd-425c-84db-9eec3743cde4'	System	25 Sep 2020 00:07:44
User entered 'None (1)'	System	25 Sep 2020 00:07:44

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:07:05', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '53ec3aca-c2fd-425c-84db-9eec3743cde4' User entered 'No (N)'	System	25 Sep 2020 00:07:44
	System	25 Sep 2020 00:07:44

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:07:21', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '53ec3aca-c2fd-425c-84db-9eec3743cde4' User entered 'No (N)'	System	25 Sep 2020 00:07:44
	System	25 Sep 2020 00:07:44



US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:07:38', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '53ec3aca-c2fd-425c-84db-9eec3743cde4'	System	25 Sep 2020 00:07:44
User entered 'None (1)'	System	25 Sep 2020 00:07:44

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:07:41', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '53ec3aca-c2fd-425c-84db-9eec3743cde4' User entered '24 Sep 2020 20:07'	System	25 Sep 2020 00:07:44
	System	25 Sep 2020 00:07:44

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:32', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4902b144-86c4-4e92-9c07-ce9705b5889a' User entered 'None (0)'	System	18 Sep 2020 21:06:58
	System	18 Sep 2020 21:06:58

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:34', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4902b144-86c4-4e92-9c07-ce9705b5889a' User entered 'None (0)'	System	18 Sep 2020 21:06:58
	System	18 Sep 2020 21:06:58

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:37', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4902b144-86c4-4e92-9c07-ce9705b5889a' User entered 'None (0)'	System	18 Sep 2020 21:06:58
	System	18 Sep 2020 21:06:58



US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:40', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4902b144-86c4-4e92-9c07-ce9705b5889a' User entered 'None (0)'	System	18 Sep 2020 21:06:58
	System	18 Sep 2020 21:06:58

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:42', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4902b144-86c4-4e92-9c07-ce9705b5889a' User entered 'None (0)'	System	18 Sep 2020 21:06:58
	System	18 Sep 2020 21:06:58

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:45', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4902b144-86c4-4e92-9c07-ce9705b5889a' User entered 'None (0)'	System	18 Sep 2020 21:06:58
	System	18 Sep 2020 21:06:58

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:50', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4902b144-86c4-4e92-9c07-ce9705b5889a' User entered 'No (N)'	System	18 Sep 2020 21:06:58
	System	18 Sep 2020 21:06:58

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-18T17:06:55', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4902b144-86c4-4e92-9c07-ce9705b5889a' User entered '18 Sep 2020 17:06'	System	18 Sep 2020 21:06:58
	System	18 Sep 2020 21:06:58

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Sep 2020 16:56'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Sep 2020 19:26'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:03:53



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Sep 2020 20:21'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 2'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:50:13', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4b007d2e-7113-4260-af80-713b948f3e33'	System	19 Sep 2020 23:51:12
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Sep 2020 23:51:12

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:50:21', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4b007d2e-7113-4260-af80-713b948f3e33'	System	19 Sep 2020 23:51:12
User entered 'Some interference with activity (2)'	System	19 Sep 2020 23:51:12

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:50:29', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4b007d2e-7113-4260-af80-713b948f3e33'	System	19 Sep 2020 23:51:12
User entered 'No interference with activity (1)'	System	19 Sep 2020 23:51:12

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:50:37', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4b007d2e-7113-4260-af80-713b948f3e33'	System	19 Sep 2020 23:51:12
User entered 'No interference with activity (1)'	System	19 Sep 2020 23:51:12

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:50:46', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4b007d2e-7113-4260-af80-713b948f3e33'	System	19 Sep 2020 23:51:12
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Sep 2020 23:51:12



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:50:56', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4b007d2e-7113-4260-af80-713b948f3e33'	System	19 Sep 2020 23:51:12
User entered 'No interference with activity (1)'	System	19 Sep 2020 23:51:12

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:51:03', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4b007d2e-7113-4260-af80-713b948f3e33' User entered 'No (N)'	System	19 Sep 2020 23:51:12
	System	19 Sep 2020 23:51:12

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-19T19:51:09', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4b007d2e-7113-4260-af80-713b948f3e33' User entered '19 Sep 2020 19:51'	System	19 Sep 2020 23:51:12
	System	19 Sep 2020 23:51:12

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 3'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:31', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '239e13aa-f9a0-4e15-8ed3-884493f6b203'	System	21 Sep 2020 00:33:01
User entered 'No interference with activity (1)'	System	21 Sep 2020 00:33:01

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:40', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '239e13aa-f9a0-4e15-8ed3-884493f6b203' User entered 'None (0)'	System	21 Sep 2020 00:33:01
	System	21 Sep 2020 00:33:01



US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:44', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '239e13aa-f9a0-4e15-8ed3-884493f6b203' User entered 'None (0)'	System	21 Sep 2020 00:33:01
	System	21 Sep 2020 00:33:01

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:46', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '239e13aa-f9a0-4e15-8ed3-884493f6b203' User entered 'None (0)'	System	21 Sep 2020 00:33:01
	System	21 Sep 2020 00:33:01

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:48', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '239e13aa-f9a0-4e15-8ed3-884493f6b203' User entered 'None (0)'	System	21 Sep 2020 00:33:01
	System	21 Sep 2020 00:33:01

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:50', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '239e13aa-f9a0-4e15-8ed3-884493f6b203' User entered 'None (0)'	System	21 Sep 2020 00:33:01
	System	21 Sep 2020 00:33:01

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:53', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '239e13aa-f9a0-4e15-8ed3-884493f6b203' User entered 'No (N)'	System	21 Sep 2020 00:33:01
	System	21 Sep 2020 00:33:01

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-20T20:32:58', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '239e13aa-f9a0-4e15-8ed3-884493f6b203' User entered '20 Sep 2020 20:32'	System	21 Sep 2020 00:33:01
	System	21 Sep 2020 00:33:01

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:03:53



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 4'	System	18 Sep 2020 21:03:53

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:36', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '676b2c00-7d1e-4f37-b3f4-82d01395f1c7' User entered 'None (0)'	System	22 Sep 2020 00:24:54
	System	22 Sep 2020 00:24:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:38', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '676b2c00-7d1e-4f37-b3f4-82d01395f1c7' User entered 'None (0)'	System	22 Sep 2020 00:24:54
	System	22 Sep 2020 00:24:54

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:41', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '676b2c00-7d1e-4f37-b3f4-82d01395f1c7' User entered 'None (0)'	System	22 Sep 2020 00:24:54
	System	22 Sep 2020 00:24:54

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:43', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '676b2c00-7d1e-4f37-b3f4-82d01395f1c7' User entered 'None (0)'	System	22 Sep 2020 00:24:54
	System	22 Sep 2020 00:24:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:45', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '676b2c00-7d1e-4f37-b3f4-82d01395f1c7' User entered 'None (0)'	System	22 Sep 2020 00:24:54
	System	22 Sep 2020 00:24:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:47', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '676b2c00-7d1e-4f37-b3f4-82d01395f1c7' User entered 'None (0)'	System	22 Sep 2020 00:24:54
	System	22 Sep 2020 00:24:54

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '676b2c00-7d1e-4f37-b3f4-82d01395f1c7' User entered 'No (N)'	System	22 Sep 2020 00:24:54
	System	22 Sep 2020 00:24:54



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-21T20:24:52', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '676b2c00-7d1e-4f37-b3f4-82d01395f1c7' User entered '21 Sep 2020 20:24'	System	22 Sep 2020 00:24:54
	System	22 Sep 2020 00:24:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 5'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '84937f63-3d43-4bd6-aad7-2f196799c8a5' User entered 'None (0)'	System	22 Sep 2020 16:03:25
	System	22 Sep 2020 16:03:25

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:51', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '84937f63-3d43-4bd6-aad7-2f196799c8a5' User entered 'None (0)'	System	22 Sep 2020 16:03:25
	System	22 Sep 2020 16:03:25

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:54', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '84937f63-3d43-4bd6-aad7-2f196799c8a5' User entered 'None (0)'	System	22 Sep 2020 16:03:25
	System	22 Sep 2020 16:03:25

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:55', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '84937f63-3d43-4bd6-aad7-2f196799c8a5' User entered 'None (0)'	System	22 Sep 2020 16:03:25
	System	22 Sep 2020 16:03:25



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:57', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '84937f63-3d43-4bd6-aad7-2f196799c8a5' User entered 'None (0)'	System	22 Sep 2020 16:03:25
	System	22 Sep 2020 16:03:25

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:01:58', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '84937f63-3d43-4bd6-aad7-2f196799c8a5' User entered 'None (0)'	System	22 Sep 2020 16:03:25
	System	22 Sep 2020 16:03:25

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:02:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '84937f63-3d43-4bd6-aad7-2f196799c8a5' User entered 'No (N)'	System	22 Sep 2020 16:03:25
	System	22 Sep 2020 16:03:25

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-22T12:02:05', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '84937f63-3d43-4bd6-aad7-2f196799c8a5' User entered '22 Sep 2020 12:02'	System	22 Sep 2020 16:03:25
	System	22 Sep 2020 16:03:25

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 6'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:14:23', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6ec1fdcb-cef6-4f40-b8b1-9c9a509e8241' User entered 'None (0)'	System	24 Sep 2020 00:14:54
	System	24 Sep 2020 00:14:54



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:14:27', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6ec1fdcb-cef6-4f40-b8b1-9c9a509e8241' User entered 'No interference with activity (1)'	System	24 Sep 2020 00:14:54
	System	24 Sep 2020 00:14:54

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:14:32', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6ec1fdcb-cef6-4f40-b8b1-9c9a509e8241' User entered 'None (0)'	System	24 Sep 2020 00:14:54
	System	24 Sep 2020 00:14:54

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:14:40', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6ec1fdcb-cef6-4f40-b8b1-9c9a509e8241' User entered 'No interference with activity (1)'	System	24 Sep 2020 00:14:54
	System	24 Sep 2020 00:14:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:14:44', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6ec1fdcb-cef6-4f40-b8b1-9c9a509e8241' User entered 'None (0)'	System	24 Sep 2020 00:14:54
	System	24 Sep 2020 00:14:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:14:46', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6ec1fdcb-cef6-4f40-b8b1-9c9a509e8241' User entered 'None (0)'	System	24 Sep 2020 00:14:54
	System	24 Sep 2020 00:14:54

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:14:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6ec1fdcb-cef6-4f40-b8b1-9c9a509e8241' User entered 'No (N)'	System	24 Sep 2020 00:14:54
	System	24 Sep 2020 00:14:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-23T20:14:52', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6ec1fdcb-cef6-4f40-b8b1-9c9a509e8241' User entered '23 Sep 2020 20:14'	System	24 Sep 2020 00:14:54
	System	24 Sep 2020 00:14:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:03:53



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 7'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:07:46', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5421fc69-9c81-46c7-9b4b-422d761bbecc' User entered 'None (0)'	System	25 Sep 2020 00:08:13
	System	25 Sep 2020 00:08:13

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:07:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5421fc69-9c81-46c7-9b4b-422d761bbecc' User entered 'Some interference with activity (2)'	System	25 Sep 2020 00:08:13
	System	25 Sep 2020 00:08:13

US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:07:52', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5421fc69-9c81-46c7-9b4b-422d761bbecc' User entered 'None (0)'	System	25 Sep 2020 00:08:13
	System	25 Sep 2020 00:08:13

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:07:57', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5421fc69-9c81-46c7-9b4b-422d761bbecc' User entered 'Some interference with activity (2)'	System	25 Sep 2020 00:08:13
	System	25 Sep 2020 00:08:13

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:07:59', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5421fc69-9c81-46c7-9b4b-422d761bbecc' User entered 'None (0)'	System	25 Sep 2020 00:08:13
	System	25 Sep 2020 00:08:13

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:08:02', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5421fc69-9c81-46c7-9b4b-422d761bbecc' User entered 'None (0)'	System	25 Sep 2020 00:08:13
	System	25 Sep 2020 00:08:13



US3842040

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:08:04', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5421fc69-9c81-46c7-9b4b-422d761bbecc' User entered 'No (N)'	System	25 Sep 2020 00:08:13
	System	25 Sep 2020 00:08:13

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-24T20:08:07', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5421fc69-9c81-46c7-9b4b-422d761bbecc' User entered '24 Sep 2020 20:08'	System	25 Sep 2020 00:08:13
	System	25 Sep 2020 00:08:13

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	24 Sep 2020 00:14:54
User entered 'Day 8'	System	24 Sep 2020 00:14:54

US3842040

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 00:14:54



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 00:14:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	25 Sep 2020 00:08:13
User entered 'Day 9'	System	25 Sep 2020 00:08:13

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-27T06:26:03', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ea8810e9-205d-4bc2-9b2e-85a936e6656a' User entered 'None (0)'	System	27 Sep 2020 10:26:08
	System	27 Sep 2020 10:26:08

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-27T06:26:06', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ea8810e9-205d-4bc2-9b2e-85a936e6656a' User entered '27 Sep 2020 06:26'	System	27 Sep 2020 10:26:08
	System	27 Sep 2020 10:26:08

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 00:08:13

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 00:08:13

US3842040

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	24 Sep 2020 00:14:54
User entered 'Day 8'	System	24 Sep 2020 00:14:54

US3842040

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 00:14:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 00:14:54

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	25 Sep 2020 00:08:13
User entered 'Day 9'	System	25 Sep 2020 00:08:13

US3842040

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 12 Aug 2021 13:32:45

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-27T06:26:12', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '25c60436-e2fc-4618-9a21-f6c05e94b6e4' User entered 'None (0)'	System	27 Sep 2020 10:26:19
	System	27 Sep 2020 10:26:19

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-27T06:26:16', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '25c60436-e2fc-4618-9a21-f6c05e94b6e4' User entered '27 Sep 2020 06:26'	System	27 Sep 2020 10:26:19
	System	27 Sep 2020 10:26:19

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 00:08:13

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 00:08:13



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	24 Sep 2020 00:13:01
User entered 'Day 8'	System	24 Sep 2020 00:13:01

US3842040

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 00:13:01

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 00:13:01

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	25 Sep 2020 00:07:03
User entered 'Day 9'	System	25 Sep 2020 00:07:03

US3842040

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-27T06:26:19', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '033e5b39-102d-407c-a82d-c3b762fd0660' User entered 'No (N)'	System	27 Sep 2020 10:26:24
	System	27 Sep 2020 10:26:24

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-09-27T06:26:22', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '033e5b39-102d-407c-a82d-c3b762fd0660' User entered '27 Sep 2020 06:26'	System	27 Sep 2020 10:26:24
	System	27 Sep 2020 10:26:24



**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 00:07:03

**US3842040**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 00:07:03

**US3842040**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:24:50
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	29 Sep 2020 00:59:43

**US3842040**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:24:50
User entered '28 Sep 2020'	Christie Lyn Costanza (b) (4)	29 Sep 2020 00:59:43

**US3842040**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:24:50
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza (b) (4)	29 Sep 2020 00:59:43

**US3842040**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:24:50
User entered empty.	Christie Lyn Costanza (b) (4)	29 Sep 2020 00:59:43

**US3842040**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:25:05
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	29 Sep 2020 00:59:46

**US3842040**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '1'	System	29 Sep 2020 00:59:46



**US3842040**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:27:13
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	07 Oct 2020 00:37:20

**US3842040**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:27:13
User entered '05 Oct 2020'	Christie Lyn Costanza (b) (4)	07 Oct 2020 00:37:20

**US3842040**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:27:13
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza (b) (4)	07 Oct 2020 00:37:20

**US3842040**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:27:13
User entered empty.	Christie Lyn Costanza (b) (4)	07 Oct 2020 00:37:20

**US3842040**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:27:33
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	07 Oct 2020 00:37:24

**US3842040**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'I'	System	07 Oct 2020 00:37:24

**US3842040**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:28:07
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	12 Oct 2020 18:30:07

**US3842040**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:28:07
User entered '12 Oct 2020'	Christie Lyn Costanza (b) (4)	12 Oct 2020 18:30:07



**US3842040**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:28:07
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza (b) (4)	12 Oct 2020 18:30:07

**US3842040**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:28:07
User entered empty.	Christie Lyn Costanza (b) (4)	12 Oct 2020 18:30:07

**US3842040**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:28:27
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	12 Oct 2020 18:30:12

**US3842040**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'I'	System	12 Oct 2020 18:30:12

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:36:06
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:29:32

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:36:06
User entered '16 Oct 2020'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:29:32

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:36:06
User entered 'Clinic (Clinic)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:29:32

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'VISIT2'	System	16 Oct 2020 14:29:32



**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User accepted default value 'Pre-Dose (PREDOSE)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '16 Oct 2020'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '10:16'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '16 Oct 2020 10:16'	System	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '98.3' F	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered 'Oral (Oral)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09



**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '77'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'bpm'	System	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '22'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'breaths/min'	System	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '124'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'mmHg'	System	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '71'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'mmHg'	System	16 Oct 2020 14:30:09



US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User accepted default value 'Post-Dose (POSTDOSE)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 17:26:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 17:26:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 17:26:30
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 14:30:09
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '16 Oct 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 17:26:30
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '12:54' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 17:26:30
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '16 Oct 2020 12:54'	System	16 Oct 2020 17:26:30
User entered empty.	System	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '98.3' F reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 17:26:30
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered 'Oral (Oral)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 17:26:30
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09



**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '72' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 17:26:30
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'bpm'	System	16 Oct 2020 17:26:30
User entered empty.	System	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '18' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 17:26:30
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'breaths/min'	System	16 Oct 2020 17:26:30
User entered empty.	System	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '117' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 17:26:30
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'mmHg'	System	16 Oct 2020 17:26:30
User entered empty.	System	16 Oct 2020 14:30:09

US3842040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:13
User entered '71' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 17:26:30
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:09

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'mmHg'	System	16 Oct 2020 17:26:30
User entered empty.	System	16 Oct 2020 14:30:09



**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:32
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:23

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:38:32
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:23

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:39:39
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:53

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:39:39
User entered '16 Oct 2020'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:53

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:39:39
User entered 'Urine (URINE)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:53

US3842040

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:39:39
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 14:46:36
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:46:36
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 14:30:53
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:53

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:39:39
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:53

US3842040

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:39:39
User closed query 'Per CDM: "Was FSH sample collected?" is No, however collection date and time is recorded. Please review and update correctly, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:35:04
Query 'Per CDM: "Was FSH sample collected?" is No, however collection date and time is recorded. Please review and update correctly, else clarify. Thank you. ' answered with 'data entry error, FSH sample was not collected, corrected' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 21:37:01
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 21:36:22
User opened query 'Per CDM: "Was FSH sample collected?" is No, however collection date and time is recorded. Please review and update correctly, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:28:55
User entered '16 Oct 2020'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:53



US3842040

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per CDM: "Was FSH sample collected?" is No, however collection time is recorded. Please review and update correctly, else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 01:41:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:39:39
Query 'Per CDM: "Was FSH sample collected?" is No, however collection time is recorded. Please review and update correctly, else clarify. Thank you. ' answered with 'no FSH sample was collected' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	02 Nov 2020 03:42:43
User entered empty; reason for change New Information	Zoraida Cruz (b) (4) (b) (4)	02 Nov 2020 03:40:58
User opened query 'Per CDM: "Was FSH sample collected?" is No, however collection time is recorded. Please review and update correctly, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:36:24
Query 'Per CDM: "Was FSH sample collected?" is No, however collection date and time is recorded. Please review and update correctly, else clarify. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:36:09
User opened query 'Per CDM: "Was FSH sample collected?" is No, however collection date and time is recorded. Please review and update correctly, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:35:17
User entered '09:53'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:53

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered empty.	System	26 Oct 2020 21:36:22
User entered '16 Oct 2020 09:53'	System	16 Oct 2020 14:30:53

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:40:26
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 16:36:27

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:40:26
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 16:36:27

US3842040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

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)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:40:26
User entered empty.	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 16:36:27

US3842040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 16:36:27

US3842040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:40:26
User entered '16 Oct 2020'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 16:36:27

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:40:26
User entered '12:18'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 16:36:27



**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '16 Oct 2020 12:18'	System	16 Oct 2020 16:36:27

US3842040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:40:26
User entered 'Left Arm (LEFT ARM)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 16:36:27

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:40:26
User entered 'ONCE'	System	16 Oct 2020 16:36:27

US3842040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:45:24
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	19 Oct 2020 14:58:42

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:45:24
User entered '16 Oct 2020'	Christie Lyn Costanza (b) (4)	19 Oct 2020 14:58:42

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:45:24
User entered '10:52'	Christie Lyn Costanza (b) (4)	19 Oct 2020 14:58:42

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '16 Oct 2020 10:52'	System	19 Oct 2020 14:58:42



**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:45:41
User entered '16 Oct 2020'	Christie Lyn Costanza (b) (4)	19 Oct 2020 14:59:08

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Christie Lyn Costanza (b) (4)	19 Oct 2020 14:59:08

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:45:41
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	19 Oct 2020 14:59:08

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:45:41
User entered '10:55'	Christie Lyn Costanza (b) (4)	19 Oct 2020 14:59:08

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '16 Oct 2020 10:55'	System	19 Oct 2020 14:59:08

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Christie Lyn Costanza (b) (4)	19 Oct 2020 14:59:08

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:45:41
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	19 Oct 2020 14:59:08

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:32:45**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:45:41
User entered empty.	Christie Lyn Costanza (b) (4)	19 Oct 2020 14:59:08



**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered empty.	System	19 Oct 2020 14:59:08

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:45:53
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	16 Oct 2020 14:30:16

**US3842040**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '1'	System	16 Oct 2020 14:30:16

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:57:53', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '9f4665ef-ab01-478a-aa42-04e2a96d6ec2' User entered 'Yes (Y)'	System	16 Oct 2020 16:58:08
	System	16 Oct 2020 16:58:08

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:57:59', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '9f4665ef-ab01-478a-aa42-04e2a96d6ec2' User entered '98.3'	System	16 Oct 2020 16:58:08
	System	16 Oct 2020 16:58:08

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:02', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '9f4665ef-ab01-478a-aa42-04e2a96d6ec2'	System	16 Oct 2020 16:58:08
User entered 'No (N)'	System	16 Oct 2020 16:58:08

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:06', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '9f4665ef-ab01-478a-aa42-04e2a96d6ec2'	System	16 Oct 2020 16:58:08
User entered '16 Oct 2020 12:58'	System	16 Oct 2020 16:58:08



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '16 Oct 2020 12:38'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '16 Oct 2020 15:08'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:03', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f9fdebe0-cf84-4e53-aaa2-f681db70fe32'	System	16 Oct 2020 22:54:18
User entered 'Yes (Y)'	System	16 Oct 2020 22:54:18

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:08', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f9fdebe0-cf84-4e53-aaa2-f681db70fe32' User entered '97.8'	System	16 Oct 2020 22:54:18
	System	16 Oct 2020 22:54:18

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:11', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f9fdebe0-cf84-4e53-aaa2-f681db70fe32'	System	16 Oct 2020 22:54:18
User entered 'No (N)'	System	16 Oct 2020 22:54:18

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:15', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f9fdebe0-cf84-4e53-aaa2-f681db70fe32'	System	16 Oct 2020 22:54:18
User entered '16 Oct 2020 18:54'	System	16 Oct 2020 22:54:18

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '16 Oct 2020 16:03'	System	16 Oct 2020 16:36:27



US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 2'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:09:47', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '1bddd43e-eb37-4636-89dd-a82c3915f1a3' User entered 'Yes (Y)'	System	18 Oct 2020 01:10:09
	System	18 Oct 2020 01:10:09

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:09:52', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '1bddd43e-eb37-4636-89dd-a82c3915f1a3' User entered '97.8'	System	18 Oct 2020 01:10:09
	System	18 Oct 2020 01:10:09

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:10:04', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '1bddd43e-eb37-4636-89dd-a82c3915f1a3'	System	18 Oct 2020 01:10:09
User entered 'No (N)'	System	18 Oct 2020 01:10:09

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:10:08', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '1bddd43e-eb37-4636-89dd-a82c3915f1a3' User entered '17 Oct 2020 21:10'	System	18 Oct 2020 01:10:09
	System	18 Oct 2020 01:10:09

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 16:36:27



US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 3'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:04:38', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e0d02e80-69ba-454a-b94c-a1848a00d8d3' User entered 'Yes (Y)'	System	18 Oct 2020 21:05:02
	System	18 Oct 2020 21:05:02

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:04:42', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e0d02e80-69ba-454a-b94c-a1848a00d8d3' User entered '97.8'	System	18 Oct 2020 21:05:02
	System	18 Oct 2020 21:05:02

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:04:51', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e0d02e80-69ba-454a-b94c-a1848a00d8d3' User entered 'Yes (Y)'	System	18 Oct 2020 21:05:02
	System	18 Oct 2020 21:05:02

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'acknowledged' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 10:14:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Christie Lyn Costanza	19 Oct 2020 14:42:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:04:56', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e0d02e80-69ba-454a-b94c-a1848a00d8d3'	(b) (4)	
User entered '1'	System	18 Oct 2020 21:05:02
	System	18 Oct 2020 21:05:02
	System	18 Oct 2020 21:05:02

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:04:56', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e0d02e80-69ba-454a-b94c-a1848a00d8d3' User entered '0'	System	18 Oct 2020 21:05:02
	System	18 Oct 2020 21:05:02

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e0d02e80-69ba-454a-b94c-a1848a00d8d3' User entered '18 Oct 2020 17:05'	System	18 Oct 2020 21:05:02
	System	18 Oct 2020 21:05:02

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 16:36:27



US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 4'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:18:29', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6d685393-6350-418b-a9b6-b08f52b74130' User entered 'Yes (Y)'	System	19 Oct 2020 23:18:53
	System	19 Oct 2020 23:18:53

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:18:36', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6d685393-6350-418b-a9b6-b08f52b74130' User entered '97.8'	System	19 Oct 2020 23:18:53
	System	19 Oct 2020 23:18:53

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:18:41', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6d685393-6350-418b-a9b6-b08f52b74130'	System	19 Oct 2020 23:18:53
User entered 'Yes (Y)'	System	19 Oct 2020 23:18:53

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted to confirm medication, reason, dose, and frequency, added to ConMed EDC' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 10:14:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Malithi Desilva (b) (4)	04 Nov 2020 19:21:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:18:46', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6d685393-6350-418b-a9b6-b08f52b74130'	System	19 Oct 2020 23:18:53
User entered '1'	System	19 Oct 2020 23:18:53

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:18:46', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6d685393-6350-418b-a9b6-b08f52b74130'	System	19 Oct 2020 23:18:53
User entered '0'	System	19 Oct 2020 23:18:53

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:18:50', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6d685393-6350-418b-a9b6-b08f52b74130' User entered '19 Oct 2020 19:18'	System	19 Oct 2020 23:18:53
	System	19 Oct 2020 23:18:53



US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 5'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:17', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ea7258f5-f994-4669-a2bc-97db755f6fe1' User entered 'Yes (Y)'	System	20 Oct 2020 21:41:44
	System	20 Oct 2020 21:41:44

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:21', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ea7258f5-f994-4669-a2bc-97db755f6fe1' User entered '97.8'	System	20 Oct 2020 21:41:44
	System	20 Oct 2020 21:41:44

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:24', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ea7258f5-f994-4669-a2bc-97db755f6fe1' User entered 'Yes (Y)'	System	20 Oct 2020 21:41:44
	System	20 Oct 2020 21:41:44

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted to confirm medication, reason, dose, and frequency, added to ConMed EDC' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 10:14:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Malithi Desilva (b) (4)	04 Nov 2020 19:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:27', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ea7258f5-f994-4669-a2bc-97db755f6fe1'	System	20 Oct 2020 21:41:44
User entered '1'	System	20 Oct 2020 21:41:44

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:27', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ea7258f5-f994-4669-a2bc-97db755f6fe1' User entered '0'	System	20 Oct 2020 21:41:44
	System	20 Oct 2020 21:41:44



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:42', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ea7258f5-f994-4669-a2bc-97db755f6fe1' User entered '20 Oct 2020 17:41'	System	20 Oct 2020 21:41:44
	System	20 Oct 2020 21:41:44

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 6'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:16', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '158ad6eb-2e6c-4249-81e5-cf079ef2b3ad' User entered 'Yes (Y)'	System	21 Oct 2020 18:53:31
	System	21 Oct 2020 18:53:31

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:19', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '158ad6eb-2e6c-4249-81e5-cf079ef2b3ad' User entered '97.8'	System	21 Oct 2020 18:53:31
	System	21 Oct 2020 18:53:31

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:23', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '158ad6eb-2e6c-4249-81e5-cf079ef2b3ad'	System	21 Oct 2020 18:53:31
User entered 'Yes (Y)'	System	21 Oct 2020 18:53:31

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted to confirm medication, reason, dose, and frequency, added to ConMed EDC' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 10:14:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Malithi Desilva (b) (4)	04 Nov 2020 19:22:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:26', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '158ad6eb-2e6c-4249-81e5-cf079ef2b3ad'	System	21 Oct 2020 18:53:31
User entered '1'	System	21 Oct 2020 18:53:31



US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:26', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '158ad6eb-2e6c-4249-81e5-cf079ef2b3ad' User entered '0'	System	21 Oct 2020 18:53:31
	System	21 Oct 2020 18:53:31

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:29', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '158ad6eb-2e6c-4249-81e5-cf079ef2b3ad' User entered '21 Oct 2020 14:53'	System	21 Oct 2020 18:53:31
	System	21 Oct 2020 18:53:31

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 7'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:20:44', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0a3747f2-8d33-4c19-a45d-3d10ecfb2523' User entered 'Yes (Y)'	System	23 Oct 2020 00:20:59
	System	23 Oct 2020 00:20:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:20:48', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0a3747f2-8d33-4c19-a45d-3d10ecfb2523' User entered '97.8'	System	23 Oct 2020 00:20:59
	System	23 Oct 2020 00:20:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:20:52', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0a3747f2-8d33-4c19-a45d-3d10ecfb2523'	System	23 Oct 2020 00:20:59
User entered 'Yes (Y)'	System	23 Oct 2020 00:20:59



US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted to confirm medication, reason, dose, and frequency, added to ConMed EDC' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 10:14:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Malithi Desilva (b) (4)	04 Nov 2020 19:22:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:20:54', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0a3747f2-8d33-4c19-a45d-3d10ecfb2523'	System	23 Oct 2020 00:20:59
User entered '1'	System	23 Oct 2020 00:20:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:20:54', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0a3747f2-8d33-4c19-a45d-3d10ecfb2523' User entered '0'	System	23 Oct 2020 00:20:59
	System	23 Oct 2020 00:20:59

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:20:57', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '0a3747f2-8d33-4c19-a45d-3d10ecfb2523' User entered '22 Oct 2020 20:20'	System	23 Oct 2020 00:20:59
	System	23 Oct 2020 00:20:59

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	21 Oct 2020 18:53:31
User entered 'Day 8'	System	21 Oct 2020 18:53:31

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:10', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'cec131bb-3126-4130-a744-93cd9bc5dd0e' User entered 'Yes (Y)'	System	23 Oct 2020 19:33:24
	System	23 Oct 2020 19:33:24

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:13', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'cec131bb-3126-4130-a744-93cd9bc5dd0e' User entered '97.8'	System	23 Oct 2020 19:33:24
	System	23 Oct 2020 19:33:24



US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:16', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'cec131bb-3126-4130-a744-93cd9bc5dd0e'	System	23 Oct 2020 19:33:24
User entered 'No (N)'	System	23 Oct 2020 19:33:24

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:20', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'cec131bb-3126-4130-a744-93cd9bc5dd0e' User entered '23 Oct 2020 15:33'	System	23 Oct 2020 19:33:24
	System	23 Oct 2020 19:33:24

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 18:53:31

US3842040

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:32:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 18:53:31

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:17', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4237e4df-0879-4df2-8c9c-435a702ec142'	System	16 Oct 2020 16:58:39
User entered 'None (1)'	System	16 Oct 2020 16:58:39

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:23', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4237e4df-0879-4df2-8c9c-435a702ec142'	System	16 Oct 2020 16:58:39
User entered 'No (N)'	System	16 Oct 2020 16:58:39

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:25', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4237e4df-0879-4df2-8c9c-435a702ec142'	System	16 Oct 2020 16:58:39
User entered 'No (N)'	System	16 Oct 2020 16:58:39



US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:30', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4237e4df-0879-4df2-8c9c-435a702ec142'	System	16 Oct 2020 16:58:39
User entered 'None (1)'	System	16 Oct 2020 16:58:39

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:35', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4237e4df-0879-4df2-8c9c-435a702ec142' User entered '16 Oct 2020 12:58'	System	16 Oct 2020 16:58:39
	System	16 Oct 2020 16:58:39

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '16 Oct 2020 12:38'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '16 Oct 2020 15:08'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:20', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c25a9554-4b00-44d4-8348-0c24a7e3577b' User entered 'None (1)'	System	16 Oct 2020 22:54:37
	System	16 Oct 2020 22:54:37

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:23', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c25a9554-4b00-44d4-8348-0c24a7e3577b' User entered 'No (N)'	System	16 Oct 2020 22:54:37
	System	16 Oct 2020 22:54:37

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:25', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c25a9554-4b00-44d4-8348-0c24a7e3577b' User entered 'No (N)'	System	16 Oct 2020 22:54:37
	System	16 Oct 2020 22:54:37



US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:31', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c25a9554-4b00-44d4-8348-0c24a7e3577b'	System	16 Oct 2020 22:54:37
User entered 'None (1)'	System	16 Oct 2020 22:54:37

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:34', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c25a9554-4b00-44d4-8348-0c24a7e3577b' User entered '16 Oct 2020 18:54'	System	16 Oct 2020 22:54:37
	System	16 Oct 2020 22:54:37

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '16 Oct 2020 16:03'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 2'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:10:12', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e1b3442d-0685-4cc8-a06e-0de4d1066d6a' User entered 'None (1)'	System	18 Oct 2020 01:10:58
	System	18 Oct 2020 01:10:58

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:10:15', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e1b3442d-0685-4cc8-a06e-0de4d1066d6a' User entered 'No (N)'	System	18 Oct 2020 01:10:58
	System	18 Oct 2020 01:10:58

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:10:19', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e1b3442d-0685-4cc8-a06e-0de4d1066d6a' User entered 'No (N)'	System	18 Oct 2020 01:10:58
	System	18 Oct 2020 01:10:58



US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:10:39', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e1b3442d-0685-4cc8-a06e-0de4d1066d6a' User entered 'None (1)'	System	18 Oct 2020 01:10:58
	System	18 Oct 2020 01:10:58

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:10:55', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e1b3442d-0685-4cc8-a06e-0de4d1066d6a' User entered '17 Oct 2020 21:10'	System	18 Oct 2020 01:10:58
	System	18 Oct 2020 01:10:58

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 3'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:05', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'b4a56ceb-ed42-45b8-aa3e-25eb365cb538'	System	18 Oct 2020 21:05:23
User entered 'None (1)'	System	18 Oct 2020 21:05:23

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:08', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'b4a56ceb-ed42-45b8-aa3e-25eb365cb538' User entered 'No (N)'	System	18 Oct 2020 21:05:23
	System	18 Oct 2020 21:05:23

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:13', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'b4a56ceb-ed42-45b8-aa3e-25eb365cb538' User entered 'No (N)'	System	18 Oct 2020 21:05:23
	System	18 Oct 2020 21:05:23



US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:16', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'b4a56ceb-ed42-45b8-aa3e-25eb365cb538' User entered 'None (1)'	System	18 Oct 2020 21:05:23
	System	18 Oct 2020 21:05:23

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:19', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'b4a56ceb-ed42-45b8-aa3e-25eb365cb538' User entered '18 Oct 2020 17:05'	System	18 Oct 2020 21:05:23
	System	18 Oct 2020 21:05:23

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:32:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 4'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:18:56', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c10a7dcd-8dd1-42aa-89b4-ec37e28a521d' User entered 'None (1)'	System	19 Oct 2020 23:19:18
	System	19 Oct 2020 23:19:18

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:18:59', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c10a7dcd-8dd1-42aa-89b4-ec37e28a521d' User entered 'No (N)'	System	19 Oct 2020 23:19:18
	System	19 Oct 2020 23:19:18

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:02', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c10a7dcd-8dd1-42aa-89b4-ec37e28a521d' User entered 'No (N)'	System	19 Oct 2020 23:19:18
	System	19 Oct 2020 23:19:18



US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:12', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c10a7dcd-8dd1-42aa-89b4-ec37e28a521d' User entered 'None (1)'	System	19 Oct 2020 23:19:18
	System	19 Oct 2020 23:19:18

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:15', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c10a7dcd-8dd1-42aa-89b4-ec37e28a521d' User entered '19 Oct 2020 19:19'	System	19 Oct 2020 23:19:18
	System	19 Oct 2020 23:19:18

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 5'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:47', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ba281fe9-d125-41ed-ba61-3cb0d9102ceb' User entered 'None (1)'	System	20 Oct 2020 21:42:02
	System	20 Oct 2020 21:42:02

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ba281fe9-d125-41ed-ba61-3cb0d9102ceb' User entered 'No (N)'	System	20 Oct 2020 21:42:02
	System	20 Oct 2020 21:42:02

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:54', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ba281fe9-d125-41ed-ba61-3cb0d9102ceb' User entered 'No (N)'	System	20 Oct 2020 21:42:02
	System	20 Oct 2020 21:42:02



US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:57', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ba281fe9-d125-41ed-ba61-3cb0d9102ceb' User entered 'None (1)'	System	20 Oct 2020 21:42:02
	System	20 Oct 2020 21:42:02

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:41:59', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ba281fe9-d125-41ed-ba61-3cb0d9102ceb' User entered '20 Oct 2020 17:41'	System	20 Oct 2020 21:42:02
	System	20 Oct 2020 21:42:02

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 6'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:34', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'cb659a1d-7a8d-4d03-9cb9-3c23c5d3c72b' User entered 'None (1)'	System	21 Oct 2020 18:53:49
	System	21 Oct 2020 18:53:49

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:36', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'cb659a1d-7a8d-4d03-9cb9-3c23c5d3c72b' User entered 'No (N)'	System	21 Oct 2020 18:53:49
	System	21 Oct 2020 18:53:49

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:39', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'cb659a1d-7a8d-4d03-9cb9-3c23c5d3c72b' User entered 'No (N)'	System	21 Oct 2020 18:53:49
	System	21 Oct 2020 18:53:49



US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:41', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'cb659a1d-7a8d-4d03-9cb9-3c23c5d3c72b' User entered 'None (1)'	System	21 Oct 2020 18:53:49
	System	21 Oct 2020 18:53:49

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:45', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'cb659a1d-7a8d-4d03-9cb9-3c23c5d3c72b' User entered '21 Oct 2020 14:53'	System	21 Oct 2020 18:53:49
	System	21 Oct 2020 18:53:49

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 7'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd73c53fe-441b-4a27-b075-6bfd173a84dd'	System	23 Oct 2020 00:21:17
User entered 'None (1)'	System	23 Oct 2020 00:21:17

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:03', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd73c53fe-441b-4a27-b075-6bfd173a84dd' User entered 'No (N)'	System	23 Oct 2020 00:21:17
	System	23 Oct 2020 00:21:17

US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:07', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd73c53fe-441b-4a27-b075-6bfd173a84dd' User entered 'No (N)'	System	23 Oct 2020 00:21:17
	System	23 Oct 2020 00:21:17



US3842040

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:09', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd73c53fe-441b-4a27-b075-6bfd173a84dd' User entered 'None (1)'	System	23 Oct 2020 00:21:17
	System	23 Oct 2020 00:21:17

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:12', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd73c53fe-441b-4a27-b075-6bfd173a84dd' User entered '22 Oct 2020 20:21'	System	23 Oct 2020 00:21:17
	System	23 Oct 2020 00:21:17

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:47', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '7acfa2d8-59bd-488a-aa27-c22e80538c6f' User entered 'None (0)'	System	16 Oct 2020 16:59:07
	System	16 Oct 2020 16:59:07

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '7acfa2d8-59bd-488a-aa27-c22e80538c6f' User entered 'None (0)'	System	16 Oct 2020 16:59:07
	System	16 Oct 2020 16:59:07

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:51', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '7acfa2d8-59bd-488a-aa27-c22e80538c6f' User entered 'None (0)'	System	16 Oct 2020 16:59:07
	System	16 Oct 2020 16:59:07



US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:54', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '7acfa2d8-59bd-488a-aa27-c22e80538c6f' User entered 'None (0)'	System	16 Oct 2020 16:59:07
	System	16 Oct 2020 16:59:07

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:55', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '7acfa2d8-59bd-488a-aa27-c22e80538c6f' User entered 'None (0)'	System	16 Oct 2020 16:59:07
	System	16 Oct 2020 16:59:07

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:57', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '7acfa2d8-59bd-488a-aa27-c22e80538c6f' User entered 'None (0)'	System	16 Oct 2020 16:59:07
	System	16 Oct 2020 16:59:07

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:58:59', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '7acfa2d8-59bd-488a-aa27-c22e80538c6f' User entered 'No (N)'	System	16 Oct 2020 16:59:07
	System	16 Oct 2020 16:59:07

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T12:59:02', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '7acfa2d8-59bd-488a-aa27-c22e80538c6f' User entered '16 Oct 2020 12:59'	System	16 Oct 2020 16:59:07
	System	16 Oct 2020 16:59:07

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '16 Oct 2020 12:38'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '16 Oct 2020 15:08'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 16:36:27



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:37', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6511e81e-86b0-4d8d-a50d-45e59f12aef1' User entered 'None (0)'	System	16 Oct 2020 22:54:57
	System	16 Oct 2020 22:54:57

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:40', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6511e81e-86b0-4d8d-a50d-45e59f12aef1' User entered 'None (0)'	System	16 Oct 2020 22:54:57
	System	16 Oct 2020 22:54:57

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:42', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6511e81e-86b0-4d8d-a50d-45e59f12aef1' User entered 'None (0)'	System	16 Oct 2020 22:54:57
	System	16 Oct 2020 22:54:57

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:44', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6511e81e-86b0-4d8d-a50d-45e59f12aef1' User entered 'None (0)'	System	16 Oct 2020 22:54:57
	System	16 Oct 2020 22:54:57

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:46', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6511e81e-86b0-4d8d-a50d-45e59f12aef1' User entered 'None (0)'	System	16 Oct 2020 22:54:57
	System	16 Oct 2020 22:54:57

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:47', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6511e81e-86b0-4d8d-a50d-45e59f12aef1' User entered 'None (0)'	System	16 Oct 2020 22:54:57
	System	16 Oct 2020 22:54:57

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6511e81e-86b0-4d8d-a50d-45e59f12aef1' User entered 'No (N)'	System	16 Oct 2020 22:54:57
	System	16 Oct 2020 22:54:57

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-16T18:54:52', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '6511e81e-86b0-4d8d-a50d-45e59f12aef1' User entered '16 Oct 2020 18:54'	System	16 Oct 2020 22:54:57
	System	16 Oct 2020 22:54:57



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '16 Oct 2020 16:03'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 2'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:11:11', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c736b784-2ab6-47e0-a652-cf0dbbbfe780' User entered 'None (0)'	System	18 Oct 2020 01:12:15
	System	18 Oct 2020 01:12:15

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:11:19', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c736b784-2ab6-47e0-a652-cf0dbbbfe780'	System	18 Oct 2020 01:12:15
User entered 'Some interference with activity (2)'	System	18 Oct 2020 01:12:15

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:11:27', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c736b784-2ab6-47e0-a652-cf0dbbbfe780' User entered 'None (0)'	System	18 Oct 2020 01:12:15
	System	18 Oct 2020 01:12:15

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:11:39', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c736b784-2ab6-47e0-a652-cf0dbbbfe780' User entered 'None (0)'	System	18 Oct 2020 01:12:15
	System	18 Oct 2020 01:12:15

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:11:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c736b784-2ab6-47e0-a652-cf0dbbbfe780' User entered 'None (0)'	System	18 Oct 2020 01:12:15
	System	18 Oct 2020 01:12:15



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:11:51', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c736b784-2ab6-47e0-a652-cf0dbbbfe780' User entered 'None (0)'	System	18 Oct 2020 01:12:15
	System	18 Oct 2020 01:12:15

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:11:58', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c736b784-2ab6-47e0-a652-cf0dbbbfe780' User entered 'No (N)'	System	18 Oct 2020 01:12:15
	System	18 Oct 2020 01:12:15

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-17T21:12:11', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c736b784-2ab6-47e0-a652-cf0dbbbfe780' User entered '17 Oct 2020 21:12'	System	18 Oct 2020 01:12:15
	System	18 Oct 2020 01:12:15

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 3'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:26', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '2dc23e42-276f-4dee-8fd9-4877b80bd2bd' User entered 'No interference with activity (1)'	System	18 Oct 2020 21:06:02
	System	18 Oct 2020 21:06:02

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:30', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '2dc23e42-276f-4dee-8fd9-4877b80bd2bd' User entered 'No interference with activity (1)'	System	18 Oct 2020 21:06:02
	System	18 Oct 2020 21:06:02



US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:38', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '2dc23e42-276f-4dee-8fd9-4877b80bd2bd' User entered 'None (0)'	System	18 Oct 2020 21:06:02
	System	18 Oct 2020 21:06:02

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '2dc23e42-276f-4dee-8fd9-4877b80bd2bd' User entered 'No interference with activity (1)'	System	18 Oct 2020 21:06:02
	System	18 Oct 2020 21:06:02

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:51', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '2dc23e42-276f-4dee-8fd9-4877b80bd2bd' User entered 'None (0)'	System	18 Oct 2020 21:06:02
	System	18 Oct 2020 21:06:02

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:53', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '2dc23e42-276f-4dee-8fd9-4877b80bd2bd' User entered 'None (0)'	System	18 Oct 2020 21:06:02
	System	18 Oct 2020 21:06:02

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:56', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '2dc23e42-276f-4dee-8fd9-4877b80bd2bd' User entered 'No (N)'	System	18 Oct 2020 21:06:02
	System	18 Oct 2020 21:06:02

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-18T17:05:59', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '2dc23e42-276f-4dee-8fd9-4877b80bd2bd' User entered '18 Oct 2020 17:05'	System	18 Oct 2020 21:06:02
	System	18 Oct 2020 21:06:02

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 16:36:27



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 4'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:27', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '54d5fc03-3db1-4def-a7d8-258460c5df5e'	System	19 Oct 2020 23:19:51
User entered 'No interference with activity (1)'	System	19 Oct 2020 23:19:51

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:24', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '54d5fc03-3db1-4def-a7d8-258460c5df5e' User entered 'None (0)'	System	19 Oct 2020 23:19:51
	System	19 Oct 2020 23:19:51

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:34', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '54d5fc03-3db1-4def-a7d8-258460c5df5e' User entered 'No interference with activity (1)'	System	19 Oct 2020 23:19:51
	System	19 Oct 2020 23:19:51

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:37', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '54d5fc03-3db1-4def-a7d8-258460c5df5e'	System	19 Oct 2020 23:19:51
User entered 'No interference with activity (1)'	System	19 Oct 2020 23:19:51

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:40', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '54d5fc03-3db1-4def-a7d8-258460c5df5e' User entered 'None (0)'	System	19 Oct 2020 23:19:51
	System	19 Oct 2020 23:19:51

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:42', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '54d5fc03-3db1-4def-a7d8-258460c5df5e' User entered 'None (0)'	System	19 Oct 2020 23:19:51
	System	19 Oct 2020 23:19:51

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:45', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '54d5fc03-3db1-4def-a7d8-258460c5df5e' User entered 'No (N)'	System	19 Oct 2020 23:19:51
	System	19 Oct 2020 23:19:51



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-19T19:19:47', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '54d5fc03-3db1-4def-a7d8-258460c5df5e' User entered '19 Oct 2020 19:19'	System	19 Oct 2020 23:19:51
	System	19 Oct 2020 23:19:51

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 5'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:42:17', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'def65180-c3ad-4c79-bf68-a40c99912644'	System	20 Oct 2020 21:42:44
User entered 'No interference with activity (1)'	System	20 Oct 2020 21:42:44

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:42:20', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'def65180-c3ad-4c79-bf68-a40c99912644' User entered 'None (0)'	System	20 Oct 2020 21:42:44
	System	20 Oct 2020 21:42:44

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:42:22', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'def65180-c3ad-4c79-bf68-a40c99912644' User entered 'None (0)'	System	20 Oct 2020 21:42:44
	System	20 Oct 2020 21:42:44

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:42:25', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'def65180-c3ad-4c79-bf68-a40c99912644'	System	20 Oct 2020 21:42:44
User entered 'No interference with activity (1)'	System	20 Oct 2020 21:42:44



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:42:27', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'def65180-c3ad-4c79-bf68-a40c99912644' User entered 'None (0)'	System	20 Oct 2020 21:42:44
	System	20 Oct 2020 21:42:44

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:42:29', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'def65180-c3ad-4c79-bf68-a40c99912644' User entered 'None (0)'	System	20 Oct 2020 21:42:44
	System	20 Oct 2020 21:42:44

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:42:32', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'def65180-c3ad-4c79-bf68-a40c99912644' User entered 'No (N)'	System	20 Oct 2020 21:42:44
	System	20 Oct 2020 21:42:44

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-20T17:42:34', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'def65180-c3ad-4c79-bf68-a40c99912644' User entered '20 Oct 2020 17:42'	System	20 Oct 2020 21:42:44
	System	20 Oct 2020 21:42:44

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 6'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:50', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '3343617e-75a6-4821-a358-a883a3a049ae' User entered 'No interference with activity (1)'	System	21 Oct 2020 18:54:12
	System	21 Oct 2020 18:54:12



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:53', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '3343617e-75a6-4821-a358-a883a3a049ae' User entered 'None (0)'	System	21 Oct 2020 18:54:12
	System	21 Oct 2020 18:54:12

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:57', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '3343617e-75a6-4821-a358-a883a3a049ae' User entered 'None (0)'	System	21 Oct 2020 18:54:12
	System	21 Oct 2020 18:54:12

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:53:59', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '3343617e-75a6-4821-a358-a883a3a049ae' User entered 'No interference with activity (1)'	System	21 Oct 2020 18:54:12
	System	21 Oct 2020 18:54:12

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:54:01', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '3343617e-75a6-4821-a358-a883a3a049ae' User entered 'None (0)'	System	21 Oct 2020 18:54:12
	System	21 Oct 2020 18:54:12

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:54:03', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '3343617e-75a6-4821-a358-a883a3a049ae' User entered 'None (0)'	System	21 Oct 2020 18:54:12
	System	21 Oct 2020 18:54:12

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:54:05', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '3343617e-75a6-4821-a358-a883a3a049ae' User entered 'No (N)'	System	21 Oct 2020 18:54:12
	System	21 Oct 2020 18:54:12

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-21T14:54:07', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '3343617e-75a6-4821-a358-a883a3a049ae' User entered '21 Oct 2020 14:54'	System	21 Oct 2020 18:54:12
	System	21 Oct 2020 18:54:12

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 16:36:27



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	16 Oct 2020 16:36:27
User entered 'Day 7'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:22', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd6d87658-ae8d-47a2-ba13-d672e3e0ba6c'	System	23 Oct 2020 00:21:47
User entered 'No interference with activity (1)'	System	23 Oct 2020 00:21:47

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:26', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd6d87658-ae8d-47a2-ba13-d672e3e0ba6c'	System	23 Oct 2020 00:21:47
User entered 'No interference with activity (1)'	System	23 Oct 2020 00:21:47

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:32:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:30', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd6d87658-ae8d-47a2-ba13-d672e3e0ba6c'	System	23 Oct 2020 00:21:47
User entered 'No interference with activity (1)'	System	23 Oct 2020 00:21:47

US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:32:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:33', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd6d87658-ae8d-47a2-ba13-d672e3e0ba6c'	System	23 Oct 2020 00:21:47
User entered 'No interference with activity (1)'	System	23 Oct 2020 00:21:47

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:35', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd6d87658-ae8d-47a2-ba13-d672e3e0ba6c' User entered 'None (0)'	System	23 Oct 2020 00:21:47
	System	23 Oct 2020 00:21:47

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:38', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd6d87658-ae8d-47a2-ba13-d672e3e0ba6c' User entered 'None (0)'	System	23 Oct 2020 00:21:47
	System	23 Oct 2020 00:21:47



US3842040

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:41', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd6d87658-ae8d-47a2-ba13-d672e3e0ba6c' User entered 'No (N)'	System	23 Oct 2020 00:21:47
	System	23 Oct 2020 00:21:47

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-22T20:21:44', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd6d87658-ae8d-47a2-ba13-d672e3e0ba6c' User entered '22 Oct 2020 20:21'	System	23 Oct 2020 00:21:47
	System	23 Oct 2020 00:21:47

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 16:36:27

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	21 Oct 2020 18:54:12
User entered 'Day 8'	System	21 Oct 2020 18:54:12

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:24', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '844b972e-ba3c-4a2a-823c-38cca6ec081a' User entered 'None (0)'	System	23 Oct 2020 19:33:30
	System	23 Oct 2020 19:33:30

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:27', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '844b972e-ba3c-4a2a-823c-38cca6ec081a' User entered '23 Oct 2020 15:33'	System	23 Oct 2020 19:33:30
	System	23 Oct 2020 19:33:30

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 18:54:12



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 18:54:12

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	23 Oct 2020 00:21:47
User entered 'Day 8'	System	23 Oct 2020 00:21:47

US3842040

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:32', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '279bb445-8386-4d5b-875c-482e2df63052'	System	23 Oct 2020 19:33:42
User entered 'None (0)'	System	23 Oct 2020 19:33:42

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:35', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '279bb445-8386-4d5b-875c-482e2df63052' User entered '23 Oct 2020 15:33'	System	23 Oct 2020 19:33:42
	System	23 Oct 2020 19:33:42

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Oct 2020 12:00'	System	23 Oct 2020 00:21:47

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 00:21:47

US3842040

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:32:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	23 Oct 2020 00:21:47
User entered 'Day 8'	System	23 Oct 2020 00:21:47

US3842040

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:38', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '8dfae131-d05e-4de6-9bf0-f571cf301a5c' User entered 'None (0)'	System	23 Oct 2020 19:33:44
	System	23 Oct 2020 19:33:44



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:41', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '8dfae131-d05e-4de6-9bf0-f571cf301a5c' User entered '23 Oct 2020 15:33'	System	23 Oct 2020 19:33:44
	System	23 Oct 2020 19:33:44

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Oct 2020 12:00'	System	23 Oct 2020 00:21:47

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 00:21:47

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	21 Oct 2020 18:54:12
User entered 'Day 8'	System	21 Oct 2020 18:54:12

US3842040

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 12 Aug 2021 13:32:45

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:44', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'be733ca1-3db0-48ac-91f8-442ad36680e6' User entered 'None (0)'	System	23 Oct 2020 19:33:51
	System	23 Oct 2020 19:33:51

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:46', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'be733ca1-3db0-48ac-91f8-442ad36680e6' User entered '23 Oct 2020 15:33'	System	23 Oct 2020 19:33:51
	System	23 Oct 2020 19:33:51

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 18:54:12

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 18:54:12



**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
Data entry locked.	System	21 Oct 2020 18:53:31
User entered 'Day 8'	System	21 Oct 2020 18:53:31

US3842040

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:32:45

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 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:50', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '19ad047e-1b40-4317-9276-d2817317965c' User entered 'No (N)'	System	23 Oct 2020 19:33:55
	System	23 Oct 2020 19:33:55

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-10-23T15:33:53', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '19ad047e-1b40-4317-9276-d2817317965c' User entered '23 Oct 2020 15:33'	System	23 Oct 2020 19:33:55
	System	23 Oct 2020 19:33:55

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 18:53:31

**US3842040**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:32:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:02:05
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 18:53:31

**US3842040**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:50:56
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	03 Nov 2020 15:00:59

**US3842040**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:50:56
User entered '26 Oct 2020'	Christie Lyn Costanza (b) (4)	03 Nov 2020 15:00:59

**US3842040**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:50:56
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza (b) (4)	03 Nov 2020 15:00:59



**US3842040**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:50:56
User entered empty.	Christie Lyn Costanza (b) (4)	03 Nov 2020 15:00:59

**US3842040**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:59:11
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	03 Nov 2020 15:01:03

**US3842040**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'I'	System	03 Nov 2020 15:01:03

**US3842040**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 20:53:48
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4)	03 Nov 2020 15:03:02
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 20:53:48
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	03 Nov 2020 15:03:02
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 20:53:48
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	03 Nov 2020 15:03:02
	Christie Lyn Costanza	
	(b) (4)	

US3842040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 20:53:48
User closed query 'please provide comment for reason contact not made' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 20:52:48
Query 'please provide comment for reason contact not made' answered with 'missed safety call, scheduled for an illness visit on 03NOV2020' (Site from CRA).	Zoraida Cruz (b) (4)	26 Feb 2021 23:46:38
User opened query 'please provide comment for reason contact not made' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 22:16:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	Christie Lyn Costanza	03 Nov 2020 15:03:02

**US3842040**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 20:53:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	03 Nov 2020 15:03:08



**US3842040**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'I'	System	03 Nov 2020 15:03:08

**US3842040**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 16:51:19
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '09 Nov 2020'	(b) (4) Christie Lyn Costanza	13 Jan 2021 16:51:19

**US3842040**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	13 Jan 2021 16:51:19
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	13 Jan 2021 16:51:19
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza	13 Jan 2021 16:51:26

**US3842040**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '1'	System	13 Jan 2021 16:51:26

**US3842040**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:08
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4)	27 Jan 2021 03:12:54
	Christie Lyn Costanza	
	(b) (4)	



**US3842040**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:08
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	27 Jan 2021 03:12:54
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:08
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	27 Jan 2021 03:12:54
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:08
User entered 'VISIT3'	System	27 Jan 2021 03:12:54

**US3842040**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza	13 Jan 2021 16:52:24

**US3842040**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered '1'	System	13 Jan 2021 16:52:24

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32
Data entry locked.	System	18 Sep 2020 21:03:53
User entered 'Day 64'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32
Data entry locked.	System	18 Sep 2020 21:03:53
User entered '18 Nov 2020 00:01'	System	18 Sep 2020 21:03:53



**US3842040**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:38:32
Data entry locked.	System	18 Sep 2020 21:03:53
User entered '22 Nov 2020 23:59'	System	18 Sep 2020 21:03:53

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-11-22T09:24:24', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ce2f2178-9b6b-4a39-a5ca-d741dd8558a6' User entered 'No (N)'	System	22 Nov 2020 14:24:55
	System	22 Nov 2020 14:24:55

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-11-22T09:24:32', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ce2f2178-9b6b-4a39-a5ca-d741dd8558a6'	System	22 Nov 2020 14:24:55
User entered 'Yes (Y)'	System	22 Nov 2020 14:24:55

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Please 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-11-22T09:24:40', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ce2f2178-9b6b-4a39-a5ca-d741dd8558a6'	System	22 Nov 2020 14:24:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 14:24:55

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-11-22T09:24:44', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'ce2f2178-9b6b-4a39-a5ca-d741dd8558a6' User entered '22 Nov 2020 09:24:44'	System	22 Nov 2020 14:24:55
	System	22 Nov 2020 14:24:55

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-02T18:05:03', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '785df69c-3ec0-4aa4-bee2-05723409f93a' User entered 'No (N)'	System	02 Dec 2020 23:05:15
	System	02 Dec 2020 23:05:15

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-02T18:05:09', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '785df69c-3ec0-4aa4-bee2-05723409f93a' User entered 'No (N)'	System	02 Dec 2020 23:05:15
	System	02 Dec 2020 23:05:15

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-02T18:05:13', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '785df69c-3ec0-4aa4-bee2-05723409f93a' User entered '02 Dec 2020 18:05:13'	System	02 Dec 2020 23:05:15
	System	02 Dec 2020 23:05:15

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-09T18:00:36', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e756fe05-d023-43a9-9ef6-c6ea1aa0f6df'	System	09 Dec 2020 23:00:47
User entered 'No (N)'	System	09 Dec 2020 23:00:47



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-09T18:00:40', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e756fe05-d023-43a9-9ef6-c6ea1aa0f6df'	System	09 Dec 2020 23:00:47
User entered 'No (N)'	System	09 Dec 2020 23:00:47

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-09T18:00:45', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e756fe05-d023-43a9-9ef6-c6ea1aa0f6df' User entered '09 Dec 2020 18:00:45'	System	09 Dec 2020 23:00:47
	System	09 Dec 2020 23:00:47

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-13T05:07:08', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'b2bf0fcf-c664-420e-953e-48d28bc1e463'	System	13 Dec 2020 10:07:37
User entered 'No (N)'	System	13 Dec 2020 10:07:37

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-13T05:07:25', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'b2bf0fcf-c664-420e-953e-48d28bc1e463'	System	13 Dec 2020 10:07:37
User entered 'No (N)'	System	13 Dec 2020 10:07:37

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-13T05:07:33', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'b2bf0fcf-c664-420e-953e-48d28bc1e463' User entered '13 Dec 2020 05:07:33'	System	13 Dec 2020 10:07:37
	System	13 Dec 2020 10:07:37



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-20T06:11:02', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '013bbf56-90e4-4fe3-8b74-79a68c98d6b8' User entered 'No (N)'	System	20 Dec 2020 11:11:14
	System	20 Dec 2020 11:11:14

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-20T06:11:07', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '013bbf56-90e4-4fe3-8b74-79a68c98d6b8' User entered 'No (N)'	System	20 Dec 2020 11:11:14
	System	20 Dec 2020 11:11:14

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-20T06:11:11', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '013bbf56-90e4-4fe3-8b74-79a68c98d6b8' User entered '20 Dec 2020 06:11:11'	System	20 Dec 2020 11:11:14
	System	20 Dec 2020 11:11:14

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-27T07:09:27', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5fc9c831-b089-49ad-bc18-be3b7a8e3e13'	System	27 Dec 2020 12:09:46
User entered 'No (N)'	System	27 Dec 2020 12:09:46

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-27T07:09:37', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5fc9c831-b089-49ad-bc18-be3b7a8e3e13'	System	27 Dec 2020 12:09:46
User entered 'No (N)'	System	27 Dec 2020 12:09:46

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2020-12-27T07:09:41', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '5fc9c831-b089-49ad-bc18-be3b7a8e3e13' User entered '27 Dec 2020 07:09:41'	System	27 Dec 2020 12:09:46
	System	27 Dec 2020 12:09:46

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-06T21:26:29', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '990c94e2-7981-4b4b-98a2-8efc1478ccf8'	System	10 Jan 2021 12:54:54
User entered 'No (N)'	System	10 Jan 2021 12:54:54



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-06T21:26:35', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '990c94e2-7981-4b4b-98a2-8efc1478ccf8'	System	10 Jan 2021 12:54:54
User entered 'No (N)'	System	10 Jan 2021 12:54:54

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-06T21:26:42', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '990c94e2-7981-4b4b-98a2-8efc1478ccf8' User entered '06 Jan 2021 21:26:42'	System	10 Jan 2021 12:54:54
	System	10 Jan 2021 12:54:54

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-10T07:54:49', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '8b2b613d-3107-43ea-b907-02f7ccdb6837'	System	10 Jan 2021 12:54:59
User entered 'No (N)'	System	10 Jan 2021 12:54:59

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-10T07:54:53', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '8b2b613d-3107-43ea-b907-02f7ccdb6837'	System	10 Jan 2021 12:54:59
User entered 'No (N)'	System	10 Jan 2021 12:54:59

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-10T07:54:56', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '8b2b613d-3107-43ea-b907-02f7ccdb6837' User entered '10 Jan 2021 07:54:56'	System	10 Jan 2021 12:54:59
	System	10 Jan 2021 12:54:59



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-17T05:36:52', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd0820142-4483-4c6c-a1d3-6dd48e1ed930'	System	17 Jan 2021 10:37:01
User entered 'No (N)'	System	17 Jan 2021 10:37:01

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-17T05:36:56', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd0820142-4483-4c6c-a1d3-6dd48e1ed930'	System	17 Jan 2021 10:37:01
User entered 'No (N)'	System	17 Jan 2021 10:37:01

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-17T05:37:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'd0820142-4483-4c6c-a1d3-6dd48e1ed930' User entered '17 Jan 2021 05:37:00'	System	17 Jan 2021 10:37:01
	System	17 Jan 2021 10:37:01

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-24T06:24:32', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '9fd5787a-a69d-4e29-b313-fdbb9dd645f2' User entered 'No (N)'	System	24 Jan 2021 11:24:38

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-24T06:24:27', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '9fd5787a-a69d-4e29-b313-fdbb9dd645f2' User entered 'No (N)'	System	24 Jan 2021 11:24:38

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-01-24T06:24:36', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '9fd5787a-a69d-4e29-b313-fdbb9dd645f2' User entered '24 Jan 2021 06:24:36'	System	24 Jan 2021 11:24:38
	System	24 Jan 2021 11:24:38

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-03T15:46:53', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '8a2ebc67-845c-4f8c-9430-91240e98fd1b' User entered 'No (N)'	System	03 Feb 2021 20:47:20
	System	03 Feb 2021 20:47:20



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-03T15:47:14', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '8a2ebc67-845c-4f8c-9430-91240e98fd1b' User entered 'No (N)'	System	03 Feb 2021 20:47:20

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-03T15:47:17', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '8a2ebc67-845c-4f8c-9430-91240e98fd1b' User entered '03 Feb 2021 15:47:17'	System	03 Feb 2021 20:47:20
	System	03 Feb 2021 20:47:20

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-07T11:43:02', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c575217f-0e8d-40c1-9b51-8d8049984d30'	System	07 Feb 2021 16:43:13
User entered 'No (N)'	System	07 Feb 2021 16:43:13

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-07T11:43:06', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c575217f-0e8d-40c1-9b51-8d8049984d30'	System	07 Feb 2021 16:43:13
User entered 'No (N)'	System	07 Feb 2021 16:43:13

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-07T11:43:10', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'c575217f-0e8d-40c1-9b51-8d8049984d30' User entered '07 Feb 2021 11:43:10'	System	07 Feb 2021 16:43:13
	System	07 Feb 2021 16:43:13



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-16T12:00:40', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '658cf815-f7b2-490a-8061-1b51e4b8a03e' User entered 'No (N)'	System	16 Feb 2021 19:50:42

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-16T12:00:43', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '658cf815-f7b2-490a-8061-1b51e4b8a03e' User entered 'No (N)'	System	16 Feb 2021 19:50:42

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-16T12:00:46', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '658cf815-f7b2-490a-8061-1b51e4b8a03e' User entered '16 Feb 2021 12:00:46'	System	16 Feb 2021 19:50:42
	System	16 Feb 2021 19:50:42

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-24T18:54:49-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'bc79535b-c325-46ea-9a26-5bea0d9207cf' User entered 'No (N)'	System	24 Feb 2021 23:55:28
	System	24 Feb 2021 23:55:28

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-24T18:54:53-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'bc79535b-c325-46ea-9a26-5bea0d9207cf' User entered 'No (N)'	System	24 Feb 2021 23:55:28
	System	24 Feb 2021 23:55:28

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-02-24T18:54:56-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'bc79535b-c325-46ea-9a26-5bea0d9207cf' User entered '24 Feb 2021 23:54:56'	System	24 Feb 2021 23:55:28
	System	24 Feb 2021 23:55:28

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-01T10:57:46-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '43858e6c-855f-4651-b7e7-2ccb8e49d6f3'	System	01 Mar 2021 15:58:00
User entered 'No (N)'	System	01 Mar 2021 15:58:00



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-01T10:57:48-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '43858e6c-855f-4651-b7e7-2ccb8e49d6f3'	System	01 Mar 2021 15:58:00
User entered 'No (N)'	System	01 Mar 2021 15:58:00

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-01T10:57:54-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '43858e6c-855f-4651-b7e7-2ccb8e49d6f3'	System	01 Mar 2021 15:58:00
User entered '01 Mar 2021 10:57:54'	System	01 Mar 2021 15:58:00

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-08T10:06:28-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'adee52d6-0d6c-4380-84e0-8634bb68d592'	System	08 Mar 2021 15:06:41
User entered 'No (N)'	System	08 Mar 2021 15:06:41

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-08T10:06:31-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'adee52d6-0d6c-4380-84e0-8634bb68d592'	System	08 Mar 2021 15:06:41
User entered 'No (N)'	System	08 Mar 2021 15:06:41

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-08T10:06:36-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'adee52d6-0d6c-4380-84e0-8634bb68d592'	System	08 Mar 2021 15:06:41
User entered '08 Mar 2021 10:06:36'	System	08 Mar 2021 15:06:41



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-14T07:21:19-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4956d6b5-955e-4569-b2c1-cdee787e455d'	System	14 Mar 2021 11:21:34
User entered 'No (N)'	System	14 Mar 2021 11:21:34

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-14T07:21:24-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4956d6b5-955e-4569-b2c1-cdee787e455d'	System	14 Mar 2021 11:21:34
User entered 'No (N)'	System	14 Mar 2021 11:21:34

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-14T07:21:31-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '4956d6b5-955e-4569-b2c1-cdee787e455d' User entered '14 Mar 2021 07:21:31'	System	14 Mar 2021 11:21:34
	System	14 Mar 2021 11:21:34

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-21T09:44:33-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '652b6399-4133-4e28-a0b5-d45de002382b'	System	21 Mar 2021 13:44:42
User entered 'No (N)'	System	21 Mar 2021 13:44:42

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-21T09:44:36-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '652b6399-4133-4e28-a0b5-d45de002382b'	System	21 Mar 2021 13:44:42
User entered 'No (N)'	System	21 Mar 2021 13:44:42

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-21T09:44:40-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '652b6399-4133-4e28-a0b5-d45de002382b' User entered '21 Mar 2021 09:44:40'	System	21 Mar 2021 13:44:42
	System	21 Mar 2021 13:44:42

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-28T05:41:21-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e8dced1a-51dc-4b94-a0f4-978216c296b7'	System	04 Apr 2021 10:41:58
User entered 'No (N)'	System	04 Apr 2021 10:41:58



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-28T05:41:28-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e8dced1a-51dc-4b94-a0f4-978216c296b7'	System	04 Apr 2021 10:41:58
User entered 'No (N)'	System	04 Apr 2021 10:41:58

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-28T05:41:37-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'e8dced1a-51dc-4b94-a0f4-978216c296b7'	System	04 Apr 2021 10:41:58
User entered '28 Mar 2021 05:41:37'	System	04 Apr 2021 10:41:58

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-04T06:41:56-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f417e948-bf01-42bb-a768-b5d947ae435b'	System	04 Apr 2021 10:42:04
User entered 'No (N)'	System	04 Apr 2021 10:42:04

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-04T06:42:00-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f417e948-bf01-42bb-a768-b5d947ae435b'	System	04 Apr 2021 10:42:04
User entered 'No (N)'	System	04 Apr 2021 10:42:04

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-04T06:42:03-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: 'f417e948-bf01-42bb-a768-b5d947ae435b'	System	04 Apr 2021 10:42:04
User entered '04 Apr 2021 06:42:03'	System	04 Apr 2021 10:42:04



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-11T06:44:31-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '1e0c417c-e561-47f5-bb24-6a1db5b3244f' User entered 'No (N)'	System	11 Apr 2021 10:44:41
	System	11 Apr 2021 10:44:41

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-11T06:44:36-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '1e0c417c-e561-47f5-bb24-6a1db5b3244f' User entered 'No (N)'	System	11 Apr 2021 10:44:41

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-11T06:44:38-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '1e0c417c-e561-47f5-bb24-6a1db5b3244f' User entered '11 Apr 2021 06:44:38'	System	11 Apr 2021 10:44:41
	System	11 Apr 2021 10:44:41

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-18T20:43:10-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '32989976-3217-4ad8-90e4-264841bd716a'	System	19 Apr 2021 00:43:18
User entered 'No (N)'	System	19 Apr 2021 00:43:18

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-18T20:43:13-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '32989976-3217-4ad8-90e4-264841bd716a'	System	19 Apr 2021 00:43:18
User entered 'No (N)'	System	19 Apr 2021 00:43:18

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-18T20:43:16-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '32989976-3217-4ad8-90e4-264841bd716a'	System	19 Apr 2021 00:43:18
User entered '18 Apr 2021 20:43:16'	System	19 Apr 2021 00:43:18

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-25T06:57:09-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '819a9f6b-79cd-4b3f-b1bc-487452d517c3'	System	29 Apr 2021 17:10:25
User entered 'No (N)'	System	29 Apr 2021 17:10:25



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-25T06:57:11-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '819a9f6b-79cd-4b3f-b1bc-487452d517c3'	System	29 Apr 2021 17:10:25
User entered 'No (N)'	System	29 Apr 2021 17:10:25

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-04-25T06:57:20-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '819a9f6b-79cd-4b3f-b1bc-487452d517c3'	System	29 Apr 2021 17:10:25
User entered '25 Apr 2021 06:57:20'	System	29 Apr 2021 17:10:25

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-05-02T06:28:37-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '515cafd1-3783-4890-a4c9-ad04e1693cf7'	System	02 May 2021 10:28:53
User entered 'No (N)'	System	02 May 2021 10:28:53

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

Have you been exposed to someone with 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 (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-05-02T06:28:42-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '515cafd1-3783-4890-a4c9-ad04e1693cf7'	System	02 May 2021 10:28:53
User entered 'No (N)'	System	02 May 2021 10:28:53

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-05-02T06:28:51-04:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '515cafd1-3783-4890-a4c9-ad04e1693cf7'	System	02 May 2021 10:28:53
User entered '02 May 2021 06:28:51'	System	02 May 2021 10:28:53



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:38:32



**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 09:38:32

**US3842040**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:32:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:38:32
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 09:38:32

US3842040

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:32:45

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-01T10:57:26-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '47946d11-6fa2-438e-b7f3-c6e428f73d02'	System	01 Mar 2021 15:57:51
User entered 'Yes (Y)'	System	01 Mar 2021 15:57:51

US3842040

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:32:45**

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-01T10:57:36-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '47946d11-6fa2-438e-b7f3-c6e428f73d02'	System	01 Mar 2021 15:57:51
User entered 'Yes (Y)'	System	01 Mar 2021 15:57:51

**US3842040**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:40:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4D046E55-79A7-4F21-A722-13EF3EA0FE5B)', Time: '2021-03-01T10:57:40-05:00', User OID: 'PatientReportedOutcome (US3842040)', ODM File OID: '47946d11-6fa2-438e-b7f3-c6e428f73d02'	System	01 Mar 2021 15:57:51
User entered '01 Mar 2021 10:57:40'	System	01 Mar 2021 15:57:51



**US3842040**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:32:50
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	27 Jan 2021 03:13:45

**US3842040**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:32:50
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '11 Dec 2020'	(b) (4) Christie Lyn Costanza (b) (4)	27 Jan 2021 03:13:45

**US3842040**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:32:50
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Christie Lyn Costanza (b) (4)	27 Jan 2021 03:13:45

**US3842040**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:32:50
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Christie Lyn Costanza (b) (4)	27 Jan 2021 03:13:45

**US3842040**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:32:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	27 Jan 2021 03:13:50

**US3842040**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:22:07
User entered 'I'	System	27 Jan 2021 03:13:50

**US3842040**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:39:42
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	27 Jan 2021 03:18:28

**US3842040**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:39:42
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '13 Jan 2021'	(b) (4) Christie Lyn Costanza (b) (4)	27 Jan 2021 03:18:28



**US3842040**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:39:42
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Christie Lyn Costanza (b) (4)	27 Jan 2021 03:18:28

**US3842040**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:39:42
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	27 Jan 2021 03:18:28
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:39:48
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	27 Jan 2021 03:18:33

**US3842040**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User entered 'I'	System	27 Jan 2021 03:18:33

**US3842040**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4)	10 Feb 2021 23:38:54
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '10 Feb 2021'	(b) (4)	10 Feb 2021 23:38:54
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	10 Feb 2021 23:38:54
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	10 Feb 2021 23:38:54
	Christie Lyn Costanza	
	(b) (4)	



**US3842040**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4)	10 Feb 2021 23:39:00
	Christie Lyn Costanza	
	(b) (4)	

**US3842040**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User entered '1'	System	10 Feb 2021 23:39:00

**US3842040**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:37
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	24 Mar 2021 20:03:19

**US3842040**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:37
User entered '15 Mar 2021'	(b) (4) Malithi Desilva (b) (4) (b) (4)	24 Mar 2021 20:03:19

**US3842040**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	24 Mar 2021 20:03:19

**US3842040**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:37
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	24 Mar 2021 20:03:19

**US3842040**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:37
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	24 Mar 2021 20:03:42

**US3842040**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User entered 'I'	System	24 Mar 2021 20:03:42



**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	16 Apr 2021 21:02:01
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered '16 Apr 2021'	Malithi Desilva (b) (4)	16 Apr 2021 21:02:01
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Malithi Desilva (b) (4)	16 Apr 2021 21:02:01
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	16 Apr 2021 21:02:01

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	16 Apr 2021 21:01:52
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered '16 Apr 2021'	Malithi Desilva (b) (4)	16 Apr 2021 21:01:52
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered '10:23'	Malithi Desilva (b) (4)	16 Apr 2021 21:01:52
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Apr 2021 10:23'	System	16 Apr 2021 21:01:52



**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered '97.9' F	Malithi Desilva (b) (4)	16 Apr 2021 21:01:52
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered 'Oral (Oral)'	Malithi Desilva (b) (4)	16 Apr 2021 21:01:52
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	16 Apr 2021 21:01:52
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered '70'	Malithi Desilva (b) (4)	16 Apr 2021 21:01:52
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Apr 2021 21:01:52

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered '16'	Malithi Desilva (b) (4)	16 Apr 2021 21:01:52
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Apr 2021 21:01:52

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered '109'	Malithi Desilva (b) (4)	16 Apr 2021 21:01:52
	(b) (4)	



**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 21:01:52

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered '70'	Malithi Desilva (b) (4)	16 Apr 2021 21:01:52
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 21:01:52

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered 'No (N)'	Malithi Desilva (b) (4)	16 Apr 2021 21:02:05
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	16 Apr 2021 21:02:05
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	16 Apr 2021 21:02:15
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered '16 Apr 2021'	Malithi Desilva (b) (4)	16 Apr 2021 21:02:15
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered '10:30'	Malithi Desilva (b) (4)	16 Apr 2021 21:02:15
	(b) (4)	



**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Apr 2021 10:30'	System	16 Apr 2021 21:02:15

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	16 Apr 2021 21:02:19
	(b) (4)	

**US3842040**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 21:02:19

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:45

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:45:50
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 00:57:25
User closed query 'Per previous query response if subject told site on 03Nov2020 that they had begun experiencing symptoms than the date of contact = 03Nov2020 per CCGs. Please review and update if needed.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 12:46:20
Query 'Per previous query response if subject told site on 03Nov2020 that they had begun experiencing symptoms than the date of contact = 03Nov2020 per CCGs. Please review and update if needed.' answered with 'noted and updated per query ' (Site from CRA).	Malithi Desilva (b) (4) (b) (4)	14 Apr 2021 20:26:18
Signature has been broken.	Malithi Desilva (b) (4) (b) (4)	14 Apr 2021 20:25:57
User entered '03 Nov 2020' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	14 Apr 2021 20:25:57
User opened query 'Per previous query response if subject told site on 03Nov2020 that they had begun experiencing symptoms than the date of contact = 03Nov2020 per CCGs. Please review and update if needed.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:01:37
User signature succeeded.	Shobha Swaminathan (b) (4)	16 Feb 2021 18:47:46
User closed query 'Per CDM: It appears that initial start date of symptoms and Contact Date are the same (03NOV2020). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 08:19:14
Query 'Per CDM: It appears that initial start date of symptoms and Contact Date are the same (03NOV2020). Please review and update accordingly.' answered with 'corrected date of contact to start date participant reported symptoms. Confirmed with Illness Visit Source note, participant verbalized symptoms starting 29OCT2020 at 03NOV2020 visit' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	05 Jan 2021 20:10:32
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	05 Jan 2021 20:09:16
User entered '29 Oct 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	05 Jan 2021 20:09:16

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:45

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: It appears that initial start date of symptoms and Contact Date are the same (03NOV2020). Please review and update accordingly.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 05:17:28
	(b) (4), (b) (6)	10 Nov 2020 19:24:31
User entered '3 Nov 2020'	Malithi Desilva (b) (4)	04 Nov 2020 21:58:03
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:45

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:45:50
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:24:31
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:35:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 15:35:54
User entered '11:00' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:35:54
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:58:03
User entered empty.	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 21:58:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:32:45**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:45:50
User entered '03 Nov 2020 11:00'	System	14 Apr 2021 20:25:57
User entered '29 Oct 2020 11:00'	System	05 Jan 2021 20:09:16
User entered '3 Nov 2020 11:00'	System	05 Nov 2020 15:35:54
User entered empty.	System	04 Nov 2020 21:58:03

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:45

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:45:50
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 21:07:24
User closed query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because visit did not occurred during a Protocol Scheduled Visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 21:07:22
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because visit did not occurred during a Protocol Scheduled Visit, thanks.' answered with 'updated' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Malithi Desilva (b) (4)	25 Nov 2020 18:19:32
	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 18:19:26
	(b) (4)	
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	25 Nov 2020 18:19:26
	(b) (4)	
User opened query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because visit did not occurred during a Protocol Scheduled Visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 00:05:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:24:31
	(b) (4)	
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Malithi Desilva (b) (4)	04 Nov 2020 21:58:03
	(b) (4)	



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:32:45**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:45:50
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:24:31
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 21:58:03

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	05 Nov 2020 15:32:47
User entered empty.	(b) (4) Malithi Desilva (b) (4)	05 Nov 2020 14:30:03

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:32:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per CDM: It appears that Day 1 record is missing as Day 2 is recorded with date of 04NOV2020 which is after the Contact date of 03NOV2020. Please reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 08:33:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:36
Query 'Per CDM: It appears that Day 1 record is missing as Day 2 is recorded with date of 04NOV2020 which is after the Contact date of 03NOV2020. Please reconcile' answered with 'Day 1 data added, keyed from illness visit RN note' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:42:40
User opened query 'Per CDM: It appears that Day 1 record is missing as Day 2 is recorded with date of 04NOV2020 which is after the Contact date of 03NOV2020. Please reconcile' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 14:41:56
User entered '4 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '0'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '99'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '97.2' F	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:30:03

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 3 (Day 3)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Nov 2020 16:36:16
	(b) (4)	



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '5 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '0'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '99'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '97.8' F	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:36:16

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 4 (Day 4)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Nov 2020 16:43:44
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '6 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '0'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '99'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '98.2' F	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:43:44

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 5 (Day 5)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Nov 2020 16:46:22
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '7 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '0'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '98'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Nov 2020 16:46:22



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '97.8' F	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:32:45

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 03 Nov 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 May 2021 08:46:06
DataPoint Verified.	Shobha Swaminathan (b) (4)	28 Apr 2021 10:35:18
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 03 Nov 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly.' answered with 'reviewed with source document and PI, updated EDC' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 19:49:18
Signature has been broken.	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 17:53:59
User entered 'Moderate (Moderate)' reason for change: Per Query Resolution	Malithi Desilva (b) (4)	20 Apr 2021 17:52:11
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 03 Nov 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	20 Apr 2021 09:14:18
DataPoint Verified.	Shobha Swaminathan (b) (4)	16 Feb 2021 18:47:46
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:06:36
	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:46:22

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 6 (Day 6)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Nov 2020 16:48:43
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '8 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '0'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '92'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '99.7' F	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:48:43

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 7 (Day 7)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Nov 2020 16:51:03
	(b) (4)	



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '9 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '0'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '95'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '98.2' F	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Moderate (Moderate)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:51:03

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 1 (Day 1)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Nov 2020 20:41:47
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:32:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Query 'Per ETRTR: Per guidelines, please add Symptoms reported prior to 03Nov20 Illness Visit Day 1, thanks.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 01:46:20
User opened query 'Per ETRTR: Per guidelines, please add Symptoms reported prior to 03Nov20 Illness Visit Day 1, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 00:06:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '3 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '0'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '97'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered '98.5' F	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'None (None)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:36
User entered 'Mild (Mild)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:41:47

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 8 (Day 8)'	(b) (4)	
	Malithi Desilva (b) (4)	11 Nov 2020 13:49:50
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:32:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Please reconcile and add days since 10Nov2020. As a reminder symptom log is to be entered within 24 hrs of illness call collection' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 01:42:29
Query 'Please reconcile and add days since 10Nov2020. As a reminder symptom log is to be entered within 24 hrs of illness call collection' answered with 'symptom log updated, team reminded of log entry timeframe' (Site from CRA).	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:46:12
User opened query 'Please reconcile and add days since 10Nov2020. As a reminder symptom log is to be entered within 24 hrs of illness call collection' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 23:13:09
User entered '10 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '93'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	11 Nov 2020 13:49:50



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.3' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Nov 2020 13:49:50

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 9 (Day 9)'	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 21:31:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:31:13
User entered '11 Nov 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 21:28:40
User entered empty.	System	17 Nov 2020 21:28:40
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:28:40

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '96' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	17 Nov 2020 21:31:13
User entered empty.	System	17 Nov 2020 21:28:40

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.3' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 21:31:13
User entered empty.	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:28:40

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:28:40

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:28:40

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 21:31:13
User entered empty.	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 21:31:13
User entered empty.	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 21:31:13
User entered empty.	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 21:31:13
User entered empty.	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:31:13
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:28:40
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 15 (Day 15)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 10 (Day 10)'	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:33:16
	(b) (4)	



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '12 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '96'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	17 Nov 2020 21:33:16

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.3' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:33:16

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 16 (Day 16)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 11 (Day 11)'	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:38:23
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '13 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.2' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:32:45

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:38:23

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 17 (Day 17)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 12 (Day 12)'	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:40:25
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '14 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '95'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	17 Nov 2020 21:40:25



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:32:45

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:40:25

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 18 (Day 18)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 13 (Day 13)'	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:42:23
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '15 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '96'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	17 Nov 2020 21:42:23

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.3' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23



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Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:42:23

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 19 (Day 19)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 14 (Day 14)'	(b) (4)	
	Malithi Desilva (b) (4)	17 Nov 2020 21:44:29
	(b) (4)	



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '16 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.8' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29



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Form: Symptom Log (14)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 21:44:29

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 20 (Day 20)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 15 (Day 15)'	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '17 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:15:39

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:15:39



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '99' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	18 Nov 2020 22:18:08
User entered empty.	System	18 Nov 2020 22:15:39

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	18 Nov 2020 22:18:14
User entered '97.8' F reason for change: Data Entry Error	System	18 Nov 2020 22:18:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered '97.8' (non-conformant).	(b) (4)	18 Nov 2020 22:18:08
User entered empty.	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:15:39

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 22:18:08
User entered empty.	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 22:18:08
User entered empty.	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:15:39

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 22:18:08
User entered empty.	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 22:18:08
User entered empty.	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:18:08
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:39
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 21 (Day 21)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 16 (Day 16)'	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '18 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:15:51

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:15:51

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '100' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	18 Nov 2020 22:24:04
User entered empty.	System	18 Nov 2020 22:15:51



US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.8' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:15:51

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:24:04
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 22:24:04
User entered empty.	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 22:24:04
User entered empty.	Malithi Desilva (b) (4)	18 Nov 2020 22:15:51
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 22 (Day 22)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 17 (Day 17)'	(b) (4)	
	Malithi Desilva (b) (4)	19 Nov 2020 21:56:42
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '19 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.8' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	19 Nov 2020 21:56:42

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 23 (Day 23)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 18 (Day 18)'	(b) (4)	
	Malithi Desilva (b) (4)	23 Nov 2020 16:54:22
	(b) (4)	



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '20 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	23 Nov 2020 16:54:22

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.8' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:54:22

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 24 (Day 24)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 19 (Day 19)'	(b) (4)	
	Malithi Desilva (b) (4)	23 Nov 2020 16:56:20
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '21 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.5' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:56:20

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 25 (Day 25)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 20 (Day 20)'	(b) (4)	
	Malithi Desilva (b) (4)	23 Nov 2020 16:57:59
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '22 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	23 Nov 2020 16:57:59



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.4' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 16:57:59

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 26 (Day 26)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 21 (Day 21)'	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '23 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	25 Nov 2020 20:44:54

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	25 Nov 2020 20:44:54

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (22)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	25 Nov 2020 20:47:49
User entered empty.	System	25 Nov 2020 20:44:54

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:47:49
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:47:49
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	25 Nov 2020 20:44:54

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:47:49
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:47:49
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:47:49
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:44:54
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 27 (Day 27)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 22 (Day 22)'	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '24 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	25 Nov 2020 20:45:08

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	25 Nov 2020 20:45:08

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '99' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	25 Nov 2020 20:53:10
User entered empty.	System	25 Nov 2020 20:45:08

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.4' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:53:10
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:53:10
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:53:10
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:53:10
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:53:10
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:53:10
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:53:10
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:45:08
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 28 (Day 28)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 23 (Day 23)'	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '25 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	25 Nov 2020 20:45:23

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	25 Nov 2020 20:45:23



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (24)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	25 Nov 2020 20:55:18
User entered empty.	System	25 Nov 2020 20:45:23

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.3' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
User entered '98' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:37:02
User entered '98.3' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:55:18
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	25 Nov 2020 20:45:23

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:55:18
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 20:55:18
User entered empty.	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:55:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	25 Nov 2020 20:45:23
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 29 (Day 29)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 24 (Day 24)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Dec 2020 14:43:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 14:43:18
User entered '26 Nov 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Dec 2020 14:38:48
User entered empty.	System	10 Dec 2020 14:38:48
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (25)**

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:38:48

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (25)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (25)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Dec 2020 14:43:18
User entered empty.	System	10 Dec 2020 14:38:48



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.3' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:43:18
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:38:48

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:43:18
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:43:18
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:43:18
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:38:48
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 30 (Day 30)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 25 (Day 25)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:45:24
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '27 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '96'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Dec 2020 14:45:24

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.1' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (26)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:45:24

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 31 (Day 31)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 26 (Day 26)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '28 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:46:47

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:46:47

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '96' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (27)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Dec 2020 14:51:40
User entered empty.	System	10 Dec 2020 14:46:47

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.3' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:51:40
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:51:40
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:46:47

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:51:40
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:51:40
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:51:40
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:51:40
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:46:47
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 32 (Day 32)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 27 (Day 27)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (28)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '29 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:47:01

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (28)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:47:01



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '96' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (28)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Dec 2020 14:55:31
User entered empty.	System	10 Dec 2020 14:47:01

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.1' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:55:31
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:47:01

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:55:31
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (28)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:04:37
Signature has been broken.	Christie Lyn Costanza	26 Apr 2021 20:03:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Christie Lyn Costanza	26 Apr 2021 20:03:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 14:47:01



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Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:55:31
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:55:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:01
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 33 (Day 33)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 28 (Day 28)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '30 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:47:22

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:47:22

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (29)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (29)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Dec 2020 14:58:31
User entered empty.	System	10 Dec 2020 14:47:22



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.1' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:58:31
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	



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Form: Symptom Log (29)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:47:22

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Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:58:31
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:58:31
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:58:31
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:58:31
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	



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Form: Symptom Log (29)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 14:58:31
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:47:22
	(b) (4)	

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Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
Signature has been broken.	(b) (4)	
	Malithi Desilva (b) (4)	27 Apr 2021 15:50:47
User entered 'Day 35 (Day 35)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 15:50:47
User signature succeeded.	(b) (4)	
	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 34 (Day 34)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 29 (Day 29)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User closed query 'Per CDM: Per sponsor review, please verify and update the 'Dates' of 'Symptom Days 34 and 35, else clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:59:50
Query 'Per CDM: Per sponsor review, please verify and update the 'Dates' of 'Symptom Days 34 and 35, else clarify. ' answered with 'symptom dates for 34 and 35 are DEC 2nd and 3rd respectively per PI source documentation. ' (Site from DM).	Malithi Desilva (b) (4)	15 Mar 2021 18:47:46
User opened query 'Per CDM: Per sponsor review, please verify and update the 'Dates' of 'Symptom Days 34 and 35, else clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 23:17:24
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '2 Dec 2020'	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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**Form: Symptom Log (30)**

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:48:21

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Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (30)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Dec 2020 15:00:45
User entered empty.	System	10 Dec 2020 14:48:21

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Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.2' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:00:45
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	



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Form: Symptom Log (30)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:48:21

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:00:45
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	



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Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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**Form: Symptom Log (30)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:00:45
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:00:45
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Form: Symptom Log (30)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:00:45
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:21
	(b) (4)	

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Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
Signature has been broken.	(b) (4)	
	Malithi Desilva (b) (4)	27 Apr 2021 15:50:47
User entered 'Day 36 (Day 36)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 15:50:47
User signature succeeded.	(b) (4)	
	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 35 (Day 35)' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:54:21
User entered 'Day 30 (Day 30)'	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (31)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '3 Dec 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:48:48

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (31)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:48:48

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (31)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '99' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:02:11
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered '%'	System	10 Dec 2020 15:02:11
User entered empty.	System	10 Dec 2020 14:48:48

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.2' F reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:02:11
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:02:11
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 15:02:11
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 15:02:11
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 15:02:11
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Dec 2020 15:02:11
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:02:11
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:02:11
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 15:02:11
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:48:48

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:02:11
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:02:11
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:02:11
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 15:02:11
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:02:11
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:02:11
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:02:11
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (31)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 15:02:11
User entered empty.	Malithi Desilva (b) (4)	10 Dec 2020 14:48:48
	(b) (4)	

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 1 (Day 1)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '29 Oct 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered empty.	System	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (32)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

**Runny Nose (Rhinorrhea)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:49:44

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (33)

Generated On: 12 Aug 2021 13:32:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 2 (Day 2)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '30 Oct 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered empty.	System	04 Jan 2021 18:54:21



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (33)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (33)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:21

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 3 (Day 3)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '31 Oct 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered empty.	System	04 Jan 2021 18:54:39

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Generated On: 12 Aug 2021 13:32:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Generated On: 12 Aug 2021 13:32:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Generated On: 12 Aug 2021 13:32:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

**Runny Nose (Rhinorrhea)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (34)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:39

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 4 (Day 4)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '1 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (35)

Generated On: 12 Aug 2021 13:32:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	04 Jan 2021 18:55:13
User entered '0'	(b) (4)	
	Malithi Desilva (b) (4)	04 Jan 2021 18:54:56
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered empty.	System	04 Jan 2021 18:54:56

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (35)

Generated On: 12 Aug 2021 13:32:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

**Runny Nose (Rhinorrhea)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:54:56

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Day 5 (Day 5)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '2 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered empty.	System	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (36)

Generated On: 12 Aug 2021 13:32:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (36)

Generated On: 12 Aug 2021 13:32:45

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:04:37
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:55:13

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered 'Day 34 (Day 34)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered '1 Dec 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
User entered empty.	System	27 Apr 2021 15:50:47



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (37)

Generated On: 12 Aug 2021 13:32:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Symptom Log (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Symptom Log (37)

Generated On: 12 Aug 2021 13:32:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:29
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:19:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	27 Apr 2021 15:50:47

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:38
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:08:48
User entered '3 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:00:55

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:38
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:08:48
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:00:55

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:38
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:08:48
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	07 Nov 2020 20:45:57
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated added to AE folder' (Site from System).	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:10:56
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	04 Nov 2020 22:00:55
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:00:55

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:38
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:08:48
User entered '3 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:00:55

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:38
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:08:48
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:00:55

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:38
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:08:48
User entered empty.	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:00:55

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Folder: Covid-19 Assessment 03 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:38
User closed query 'Per CDM: Was this diagnostic test performed at a lab other than the Study Central Lab? Is marked YES but Preclarus positive central lab result present; Please review and reconcile the data. Else clarify. Thank you! ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 11:23:11
Query 'Per CDM: Was this diagnostic test performed at a lab other than the Study Central Lab? Is marked YES but Preclarus positive central lab result present; Please review and reconcile the data. Else clarify. Thank you! ' answered with 'The participant was tested 2 times on the same day at the study site. One test is sent to Preclarus (results available in 7 to 10 days). The test sent to University Hospital have results posted on the same day. ' (Site from DM).	Mario Portilla (b) (4)	09 Apr 2021 15:18:00
User opened query 'Per CDM: Was this diagnostic test performed at a lab other than the Study Central Lab? Is marked YES but Preclarus positive central lab result present; Please review and reconcile the data. Else clarify. Thank you! ' (Site from DM).	(b) (4)	09 Apr 2021 07:16:17
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:08:48
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:00:55



**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:38
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:08:48
User entered 'University Hospital NEW JERSEY MEDICAL SCHOOL CLINICAL RESEARCH CENTER' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:44:53
User entered 'New Jersey Medical School Clinical Research Center'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:00:55

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:38
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:08:48
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:00:55

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:38
User entered 'I'	System	04 Nov 2020 22:00:55

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:37:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:37:54
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 16:37:54
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:57:28
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:37:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:37:54
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 16:37:54
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:57:28
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28



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**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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**Folder: Covid-19 Assessment 03 Nov 2020**

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**Generated On: 12 Aug 2021 13:32:45**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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**Folder: Covid-19 Assessment 03 Nov 2020**

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:54:47
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:37:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:37:54
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 16:37:54
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:57:28
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered '8 Nov 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:54:47
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 13 (10NOV2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 08:48:05
	(b) (4), (b) (6)	26 Apr 2021 20:05:55
Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 13 (10NOV2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' answered with 'updated EDC end date to reflect participants Day 13 O2 saturation. ' (Site from DM). DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	22 Apr 2021 13:34:08
Signature has been broken.	Malithi Desilva (b) (4) (b) (4)	22 Apr 2021 13:32:31
User entered '10 Nov 2020' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	22 Apr 2021 13:32:31
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 13 (10NOV2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	21 Apr 2021 13:15:15
	Shobha Swaminathan (b) (4)	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered '8 Nov 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:54:47
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered '92' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:54:47
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 23:39:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 23:39:29
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	06 Nov 2020 23:39:29
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:57:28
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:37:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:37:54
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 16:37:54
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:57:28
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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**Folder: Covid-19 Assessment 03 Nov 2020**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:37:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:37:54
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 16:37:54
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:57:28
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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**Folder: Covid-19 Assessment 03 Nov 2020**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28



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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per CDM: Please provide responses for Evidence of Shock and Evidence of Pneumonia sections of this form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 09:52:59
Query 'Per CDM: Please provide responses for Evidence of Shock and Evidence of Pneumonia sections of this form.' answered with 'updated responses on form confirmed with illness visit source document' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	05 Jan 2021 20:12:55
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	05 Jan 2021 20:11:22
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	05 Jan 2021 20:11:22
User opened query 'Per CDM: Please provide responses for Evidence of Shock and Evidence of Pneumonia sections of this form.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:08:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:13
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	05 Jan 2021 20:12:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	05 Jan 2021 20:12:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4)	05 Nov 2020 15:57:28
	(b) (4)	

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28



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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	05 Jan 2021 20:12:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	05 Jan 2021 20:12:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4)	05 Nov 2020 15:57:28
	(b) (4)	

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:16
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	05 Jan 2021 20:12:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	05 Jan 2021 20:12:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4)	05 Nov 2020 15:57:28
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	05 Jan 2021 20:12:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	05 Jan 2021 20:12:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4)	05 Nov 2020 15:57:28
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User closed query 'Per CDM: Please provides responses for Evidence of Pneumonia. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:32:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Query 'Per CDM: Please provides responses for Evidence of Pneumonia. ' answered with 'updated flow sheet and eCRF with the assessment date.' (Site from DM).	(b) (4) Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 22:15:58
DataPoint Un-verified.	Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 22:15:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 22:15:25
User opened query 'Per CDM: Please provides responses for Evidence of Pneumonia. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 20:14:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28



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Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	15 Feb 2021 22:15:25
User entered '10 Nov 2020' reason for change: Per	(b) (4)	
Query Resolution	Zoraida Cruz (b) (4)	15 Feb 2021 22:15:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4)	05 Nov 2020 15:57:28
	(b) (4)	

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 22:15:25
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 22:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:15
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 22:15:25
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 22:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

US3842040

Folder: Covid-19 Assessment 03 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:32:45

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:37:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:37:54
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 16:37:54
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:57:28
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

**US3842040**

**Folder: Covid-19 Assessment 03 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:43
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:15:51
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 15:57:28

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Folder: Covid-19 Assessment 03 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:32:45

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:47
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
Signature has been broken.	(b) (4)	24 Feb 2021 18:13:36
	Mario Portilla (b) (4)	
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Mario Portilla (b) (4)	24 Feb 2021 18:13:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'No (N)'	Malithi Desilva (b) (4)	05 Nov 2020 14:30:57
	(b) (4)	

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Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:45

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD central labs has an Illness Swab sample dated 17-Feb-2021 with Accession No: 1F652998885 (per Preclarus). However, there is no corresponding record in EDC. Kindly review and if required please consider initiating a Covid-19 Assessment folder and make updates in EDC and Preclarus as appropriate. Else, clarify. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Shobha Swaminathan	29 Apr 2021 09:33:34 28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:14:50
User entered '16 Feb 2021' reason for change: Data Entry Error	Christie Lyn Costanza (b) (4)	26 Apr 2021 21:14:00
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD central labs has an Illness Swab sample dated 17-Feb-2021 with Accession No: 1F652998885 (per Preclarus). However, there is no corresponding record in EDC. Kindly review and if required please consider initiating a Covid-19 Assessment folder and make updates in EDC and Preclarus as appropriate. Else, clarify. Thank you.' answered with 'Per query, Your query mentions 2/17 and 2/23. participant had illness visits on 2/17/2021 and 2/23/2021 and had NP samples collected on both dates, that were submitted to a local lab and PPD lab. All samples resulted negative. Please clarify. Do you needs COVID assessment folders for both dates? This database does not provide for NP documentation on Illness visits Day 1. It only provides for documentation of blood samples.' (Site from DM).	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 21:53:43



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**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD central labs has an Illness Swab sample dated 17-Feb-2021 with Accession No: 1F652998885 (per Preclarus). However, there is no corresponding record in EDC. Kindly review and if required please consider initiating a Covid-19 Assessment folder and make updates in EDC and Preclarus as appropriate. Else, clarify. Thank you.' (Site from DM). User entered '23 Feb 2021'	(b) (4), (b) (6) (b) (4) (b) (4)	06 Apr 2021 10:42:39
	Mario Portilla (b) (4) (b) (4) (b) (4)	31 Mar 2021 23:06:09

**US3842040**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:32:45**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:14:50
User entered '16:30' reason for change: Data Entry Error	Christie Lyn Costanza	26 Apr 2021 21:14:00
User entered '12:45'	(b) (4) Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:06:09

**US3842040**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:32:45**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User entered '16 Feb 2021 16:30'	System	26 Apr 2021 21:14:00
User entered '23 Feb 2021 12:45'	System	31 Mar 2021 23:06:09

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Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:45

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	27 Apr 2021 16:26:57
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	27 Apr 2021 16:26:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:18:10
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 21:16:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:14:50
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Mario Portilla (b) (4)	31 Mar 2021 23:06:09
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:32:45**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:14:50
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:06:09

US3842040

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:07
User entered '17 Feb 2021' reason for change: Data Entry Error	Christie Lyn Costanza (b) (4)	26 Apr 2021 21:14:40
User entered '23 Feb 2021'	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:27:07

US3842040

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:07
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:27:07

US3842040

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:20
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:07
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:27:07



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Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:07
User entered '17 Feb 2021' reason for change: Data Entry Error	Christie Lyn Costanza (b) (4)	26 Apr 2021 21:14:40
User entered '23 Feb 2021'	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:27:07

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Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:27:07

US3842040

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:07
User entered empty.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:27:07

US3842040

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:17:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Christie Lyn Costanza	26 Apr 2021 21:15:58
DataPoint Un-verified.	(b) (4)	26 Apr 2021 21:15:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:07
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:27:07

US3842040

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:17:45
User entered 'UNIVERSITY HOSPITAL' reason for change: Data Entry Error	Christie Lyn Costanza	26 Apr 2021 21:15:58
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:15:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:07
User entered empty.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:27:07

US3842040

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:17:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Christie Lyn Costanza	26 Apr 2021 21:15:58
DataPoint Un-verified.	(b) (4)	26 Apr 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:15:07
User entered empty.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 23:27:07

**US3842040**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User entered '0'	System	31 Mar 2021 23:27:07

US3842040

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:45

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:43:32
User closed query 'Per ETRTR: Sample for illness visit Day 1 and symptoms were reported prior to Date of contact. Please confirm Date of Contact. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 20:43:28
Query 'Per ETRTR: Sample for illness visit Day 1 and symptoms were reported prior to Date of contact. Please confirm Date of Contact. ' answered with 'this covid 19 contact corresponds to Illness Visit 3 folder: Illness Visit Day 1 performed on 23FEB2021. Participant had 3 illness visits Day 1 performed: 03NOV20, 17FEB2021, and 23FEB2021. ' (Site from CRA).	Malithi Desilva (b) (4) (b) (4)	22 Apr 2021 18:04:11
User opened query 'Per ETRTR: Sample for illness visit Day 1 and symptoms were reported prior to Date of contact. Please confirm Date of Contact. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 14:39:59
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 17-Feb-2021 is reported under Illness Visit Day 1 in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 10:27:29
' (Site from DM).		



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Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:45

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 17-Feb-2021 is reported under Illness Visit Day 1 in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.  ' answered with 'ILLNESS day 1 on 2/23/2021 is different from illness day 1 on 2/17/2021.' (Site from DM).	Mario Portilla (b) (4) (b) (4)	26 Feb 2021 23:08:52
User entered '23 Feb 2021' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	26 Feb 2021 23:07:21
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 17-Feb-2021 is reported under Illness Visit Day 1 in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	(b) (4), (b) (6)	25 Feb 2021 06:42:50
' (Site from DM). User entered '22 Feb 2021'	Mario Portilla (b) (4) (b) (4)	24 Feb 2021 18:19:49

US3842040

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:45

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:43:32
Signature has been broken.	Christie Lyn Costanza	26 Apr 2021 20:43:07
User entered '07:40' reason for change: Data Entry Error	(b) (4) Christie Lyn Costanza	26 Apr 2021 20:43:07
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	24 Feb 2021 18:20:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:20:10
User entered '07:30' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	24 Feb 2021 18:20:10
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:19:49
User entered empty.	Mario Portilla (b) (4) (b) (4)	24 Feb 2021 18:19:49

**US3842040**

**Folder: Covid-19 Assessment 23 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:32:45**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User entered '23 Feb 2021 07:40'	System	26 Apr 2021 20:43:07
User entered '23 Feb 2021 07:30'	System	26 Feb 2021 23:07:21
User entered '22 Feb 2021 07:30'	System	24 Feb 2021 18:20:10
User entered empty.	System	24 Feb 2021 18:19:49

**US3842040**

**Folder: Covid-19 Assessment 23 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:32:45**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:43:32
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 18:19:49
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 23 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:32:45**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:43:32
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'Yes (Y)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 18:19:49
	(b) (4)	

US3842040

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:44:51
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
Signature has been broken.	(b) (4) Mario Portilla (b) (4) (b) (4)	26 Feb 2021 23:19:11
User entered '23 Feb 2021' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	26 Feb 2021 23:19:11
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:03:27
User entered '22 Feb 2021'	Mario Portilla (b) (4) (b) (4)	24 Feb 2021 18:37:46

**US3842040**

**Folder: Covid-19 Assessment 23 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:44:51
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 18:37:46
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 23 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:44:51
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 18:37:46
	(b) (4)	



US3842040

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:44:51
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit-COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:20:32
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit-COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.'	Mario Portilla (b) (4)	31 Mar 2021 23:29:35
answered with 'Per query, additional information has been added to satisfy query' (Site from DM).	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit-COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 07:46:32
User closed query 'Per GCL Lab Reconciliation: Swab Sample: Sample dated 17FEB2021 is recorded under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 07:46:32

US3842040

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Date of Test](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab Sample: Sample dated 17FEB2021 is recorded under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Else clarify, thank you.' answered with 'per query, Illness visit 17Feb2021 (1F637859567) collected NP and blood samples. Blood sample is documented in ECRF but NP missing documenting spot; Illness visit on 23Feb2021 (1F640433263) Blood sample and NP were both collected but no place to document in imedidata. Both NP samples resulted negative.' (Site from DM).	Mario Portilla (b) (4) (b) (4)	23 Mar 2021 21:13:36
User opened query 'Per GCL Lab Reconciliation: Swab Sample: Sample dated 17FEB2021 is recorded under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:11:00
User signature succeeded.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	26 Feb 2021 23:19:11
User entered '23 Feb 2021' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	26 Feb 2021 23:19:11
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:03:27
User entered '22 Feb 2021'	Mario Portilla (b) (4) (b) (4)	24 Feb 2021 18:37:46

**US3842040**

**Folder: Covid-19 Assessment 23 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:44:51
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Mario Portilla (b) (4)	24 Feb 2021 18:37:46

US3842040

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:32:45

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:44:51
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 18:37:46
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 23 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:44:51
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4) Mario Portilla (b) (4) (b) (4)	24 Feb 2021 18:37:46

**US3842040**

**Folder: Covid-19 Assessment 23 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:44:51
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'CLIA: 31D2184476/31D1085261	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 18:37:46
	(b) (4)	
Rutgers NJMS'		

**US3842040**

**Folder: Covid-19 Assessment 23 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:44:51
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 18:37:46
	(b) (4)	

**US3842040**

**Folder: Covid-19 Assessment 23 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 12 Aug 2021 13:32:45**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:30:47
User entered '0'	System	24 Feb 2021 18:37:46



**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User accepted default value 'Day 3 (Day 3)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:21:36
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:21:36
User entered '5 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User accepted default value 'Day 5 (Day 5)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

US3842040

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:32:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:21:36
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 23:35:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 23:35:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	06 Nov 2020 23:35:44
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:18:58
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:21:36
User entered '6 Nov 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4)	06 Nov 2020 23:36:02
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User accepted default value 'Day 7 (Day 7)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:32:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:21:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:40:08
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	08 Nov 2020 14:42:17
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:18:58
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58



**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:21:36
User entered '9 Nov 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 16:40:08
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User accepted default value 'Day 9 (Day 9)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:48:20
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Malithi Desilva (b) (4)	11 Nov 2020 17:04:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	11 Nov 2020 17:04:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:21:36
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	08 Nov 2020 14:42:20
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:18:58
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:48:20
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	11 Nov 2020 17:04:29
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 17:04:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:21:36
User entered empty.	Malithi Desilva (b) (4)	05 Nov 2020 14:18:58
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User accepted default value 'Day 14 (Day 14)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:32:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:48:20
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Malithi Desilva (b) (4)	16 Nov 2020 16:54:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	16 Nov 2020 16:54:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:21:36
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	08 Nov 2020 14:42:24
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:18:58
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:48:20
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	16 Nov 2020 16:54:50
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 16:54:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:21:36
User entered empty.	Malithi Desilva (b) (4)	05 Nov 2020 14:18:58
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User accepted default value 'Day 21 (Day 21)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58



US3842040

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:32:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:48:20
User closed query 'please enter in data from the source' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:49:24
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Query 'please enter in data from the source' answered with 'data entered ' (Site from CRA).	(b) (4)	08 Dec 2020 22:19:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	08 Dec 2020 22:19:11
User opened query 'please enter in data from the source' (Site from CRA).	(b) (4)	04 Dec 2020 20:05:09
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 20:04:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:21:36
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	08 Nov 2020 14:42:27
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:18:58
User entered empty.	Malithi Desilva (b) (4)	05 Nov 2020 14:18:58
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:48:20
User closed query 'please enter in data from source' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:56:15
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Query 'please enter in data from source' answered with 'data entered ' (Site from CRA).	(b) (4)	
Query 'please enter in data from source' answered with 'data entered ' (Site from CRA).	Malithi Desilva (b) (4)	08 Dec 2020 22:19:31
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4)	
User entered '23 Nov 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4)	08 Dec 2020 22:19:11
User opened query 'please enter in data from source' (Site from CRA).	(b) (4)	
User opened query 'please enter in data from source' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 20:05:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 20:04:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:21:36
User entered empty.	Malithi Desilva (b) (4)	05 Nov 2020 14:18:58
	(b) (4)	

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
User accepted default value 'Day 28 (Day 28)'	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

US3842040

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:32:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:48:20
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 14:34:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 14:34:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:21:36
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	08 Nov 2020 14:42:30
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:18:58
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:48:20
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 14:34:43
User entered '4 Dec 2020' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	10 Dec 2020 14:34:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:21:36
User entered empty.	Malithi Desilva (b) (4) (b) (4)	05 Nov 2020 14:18:58

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Mario Portilla (b) (4) (b) (4) (b) (4)	19 Feb 2021 18:52:56

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	



**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Mario Portilla (b) (4) (b) (4) (b) (4)	19 Feb 2021 18:52:56

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Mario Portilla (b) (4) (b) (4) (b) (4)	19 Feb 2021 18:52:56

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	



**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Mario Portilla (b) (4) (b) (4) (b) (4)	19 Feb 2021 18:52:56

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Mario Portilla (b) (4) (b) (4) (b) (4)	19 Feb 2021 18:52:56

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Mario Portilla (b) (4) (b) (4) (b) (4)	19 Feb 2021 18:52:56



**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	19 Feb 2021 18:52:56
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Mario Portilla (b) (4)	24 Feb 2021 17:43:03
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	24 Feb 2021 17:43:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty; reason for change Data Entry Error	(b) (4) Mario Portilla (b) (4)	24 Feb 2021 17:45:59
User entered '23 Feb 2021'	(b) (4) Mario Portilla (b) (4)	24 Feb 2021 17:43:03

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Mario Portilla (b) (4) (b) (4) (b) (4)	24 Feb 2021 17:43:23

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	24 Feb 2021 17:43:23
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:43:23
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Mario Portilla (b) (4) (b) (4) (b) (4)	24 Feb 2021 17:43:30

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	24 Feb 2021 17:43:30
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:43:30
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Mario Portilla (b) (4) (b) (4) (b) (4)	24 Feb 2021 17:43:38

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	24 Feb 2021 17:43:38
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:43:38
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Mario Portilla (b) (4) (b) (4) (b) (4)	24 Feb 2021 17:43:46

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	24 Feb 2021 17:43:46
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:43:46
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Mario Portilla (b) (4) (b) (4) (b) (4)	24 Feb 2021 17:43:55

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	24 Feb 2021 17:43:55
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:43:55
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Mario Portilla (b) (4) (b) (4) (b) (4)	24 Feb 2021 17:44:04

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	24 Feb 2021 17:44:04
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:32
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:04
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:32
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:23
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:29:42



US3842040

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:32
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 04:20:02
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'samples were collected, updated in saliva collection log ' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	08 Dec 2020 22:20:28
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:36:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:00:23
User entered '3 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:29:42

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:32
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:23
User entered 'Clinic (Clinic)'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:29:42

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:32
User entered 'SICKD1'	System	03 Nov 2020 17:29:42

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered '3 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered '11:13'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User entered '3 Nov 2020 11:13'	System	03 Nov 2020 17:37:08

US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:35:59
User closed query 'Per DM's previous queries and the CCGs this should be ND. Please reconcile and correct.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:44:00
Query 'Per DM's previous queries and the CCGs this should be ND. Please reconcile and correct.'	Mario Portilla (b) (4)	08 Apr 2021 19:29:12
answered with 'per query, information updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	08 Apr 2021 19:28:30
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Mario Portilla (b) (4)	08 Apr 2021 19:28:30
	(b) (4)	
User opened query 'Per DM's previous queries and the CCGs this should be ND. Please reconcile and correct.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 19:11:34
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User closed query 'Per CDM : As per CCG Height, Weight, and BMI will only be captured at Screening Visit, so please update as ND Not Done for Height and weight. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:32:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Mar 2021 12:31:59
Query 'Data is required. Please provide.' answered with 'per query, information has been updated' (Site from System).	Mario Portilla (b) (4)	09 Mar 2021 22:59:24
	(b) (4)	
Query 'Per CDM : As per CCG Height, Weight, and BMI will only be captured at Screening Visit, so please update as ND Not Done for Height and weight. Thank you' answered with 'per query, information updated' (Site from DM).	Mario Portilla (b) (4)	09 Mar 2021 22:59:02
	(b) (4)	
User opened query 'Data is required. Please provide.' System		09 Mar 2021 22:58:35
(Site from System).		
DataPoint Un-verified.	Mario Portilla (b) (4)	09 Mar 2021 22:58:35
	(b) (4)	



US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Height (xxx.x)

Audit	User	Time (GMT)
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 22:58:35
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 22:58:35
User opened query 'Per CDM : As per CCG Height, Weight, and BMI will only be captured at Screening Visit, so please update as ND Not Done for Height and weight. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:47:20
User signature succeeded.	Shobha Swaminathan (b) (4)	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered '158' cm	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08
DataPoint set to visible.	System	03 Nov 2020 17:29:42

US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:35:59
User closed query 'Per DM's previous queries and the CCGs this should be ND. Please reconcile and correct.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:44:05
Query 'Per DM's previous queries and the CCGs this should be ND. Please reconcile and correct.'	Mario Portilla (b) (4)	08 Apr 2021 19:30:08
answered with 'per query, information updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	08 Apr 2021 19:28:30
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Mario Portilla (b) (4)	08 Apr 2021 19:28:30
	(b) (4)	
User opened query 'Per DM's previous queries and the CCGs this should be ND. Please reconcile and correct.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 19:11:41
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 12:31:56
Query 'Data is required. Please provide.' answered with 'per query, information has been updated' (Site from System).	Mario Portilla (b) (4)	09 Mar 2021 22:59:43
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 22:58:35
DataPoint Un-verified.	Mario Portilla (b) (4)	09 Mar 2021 22:58:35
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	09 Mar 2021 22:58:35
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4)	09 Mar 2021 22:58:35
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered '80.6' kg	Malithi Desilva (b) (4)	03 Nov 2020 17:37:08
DataPoint set to visible.	(b) (4) System	03 Nov 2020 17:29:42

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered '98.5' F	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered 'Oral (Oral)'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered empty.	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered '80'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User entered 'bpm'	System	03 Nov 2020 17:37:08



**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered '16'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User entered 'breaths/min'	System	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered '122'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User entered 'mmHg'	System	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:13
User entered '68'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39
User entered 'mmHg'	System	03 Nov 2020 17:37:08

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:39



**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:47
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:44
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:16

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:47
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:06:44
User entered '3 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:16

US3842040

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:32:45

Was Blood Sample Taken for Immunologic Assessment of SARS\_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 DEC 2020 is reported in Convalescence Visit Day 28 IN PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 DEC 2020 is reported in Convalescence Visit Day 28 IN PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' answered with 'data confirmed with source documents and keyed into Convalescence Visit Day 28' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 11:52:56
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 DEC 2020 is reported in Convalescence Visit Day 28 IN PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.'	Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 17:40:59
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 DEC 2020 is reported in Convalescence Visit Day 28 IN PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 08:36:50
User entered 'Yes (Y)'	(b) (4), (b) (6) Malithi Desilva (b) (4) (b) (4)	06 Nov 2020 19:07:23 03 Nov 2020 17:37:28

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:07:23
User entered '3 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	03 Nov 2020 17:37:28

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4)	19 Feb 2021 18:22:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '17 Feb 2021'	(b) (4)	19 Feb 2021 18:22:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Clinic (Clinic)'	(b) (4)	19 Feb 2021 18:22:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	19 Feb 2021 18:22:03



**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4)	19 Feb 2021 18:50:28
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '17 Feb 2021'	(b) (4)	19 Feb 2021 18:50:28
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '11:50'	(b) (4)	19 Feb 2021 18:50:28
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '17 Feb 2021 11:50'	System	19 Feb 2021 18:50:28

US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User closed query 'Per CDM : As per CCG Height, Weight, and BMI will only be captured at Screening Visit, so please update as ND Not Done for Height and weight. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 08:34:05
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 08:33:49
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
Query 'Data is required. Please provide.' answered with 'per query, information updated' (Site from System).	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 23:01:05
Query 'Per CDM : As per CCG Height, Weight, and BMI will only be captured at Screening Visit, so please update as ND Not Done for Height and weight. Thank you' answered with 'per query: information updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 23:00:52
User opened query 'Data is required. Please provide.' System (Site from System).		09 Mar 2021 23:00:37
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 23:00:37
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 23:00:37
User opened query 'Per CDM : As per CCG Height, Weight, and BMI will only be captured at Screening Visit, so please update as ND Not Done for Height and weight. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:47:34
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:03:27
User entered '158' cm	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 18:50:28
DataPoint set to visible.	System	19 Feb 2021 18:22:03

US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Mar 2021 08:33:51
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
Query 'Data is required. Please provide.' answered with 'per query, information updated' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 23:01:18
User opened query 'Data is required. Please provide.' (Site from System).	Mario Portilla (b) (4)	09 Mar 2021 23:00:37
Signature has been broken.	(b) (4)	09 Mar 2021 23:00:37
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4)	09 Mar 2021 23:00:37
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '80.4' kg	(b) (4)	19 Feb 2021 18:50:28
DataPoint set to visible.	Mario Portilla (b) (4)	19 Feb 2021 18:22:03

US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	19 Feb 2021 18:50:42
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	19 Feb 2021 18:50:42
User entered '36.8' C reason for change: Data Entry Error	Mario Portilla (b) (4)	19 Feb 2021 18:50:42
	(b) (4)	
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Feb 2021 18:50:28
User entered '36.8' F	Mario Portilla (b) (4)	19 Feb 2021 18:50:28
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Oral (Oral)'	(b) (4)	19 Feb 2021 18:50:28
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	19 Feb 2021 18:50:28
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '76'	(b) (4)	19 Feb 2021 18:50:28
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Feb 2021 18:50:28

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '16'	(b) (4)	19 Feb 2021 18:50:28
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Feb 2021 18:50:28

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '126'	(b) (4)	19 Feb 2021 18:50:28
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Feb 2021 18:50:28

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:23:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '76'	(b) (4)	19 Feb 2021 18:50:28
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Feb 2021 18:50:28

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:24:10
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4)	19 Feb 2021 18:51:06
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:24:10
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '17 Feb 2021'	(b) (4)	19 Feb 2021 18:51:06
	Mario Portilla (b) (4)	
	(b) (4)	

US3842040

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:32:45

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:25:26
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4)	19 Feb 2021 18:51:40
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:25:26
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '17 Feb 2021'	(b) (4)	19 Feb 2021 18:51:40
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:28:30
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 23:01:30
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:28:30
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '23 Feb 2021'	(b) (4)	23 Feb 2021 23:01:30
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:28:30
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Clinic (Clinic)'	(b) (4)	23 Feb 2021 23:01:30
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	23 Feb 2021 23:01:30

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 23:05:15
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '23 Feb 2021'	(b) (4)	23 Feb 2021 23:05:15
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '11:51'	(b) (4)	23 Feb 2021 23:05:15
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Feb 2021 11:51'	System	23 Feb 2021 23:05:15

US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 08:34:45
User closed query 'Per CDM : As per CCG Height, Weight, and BMI will only be captured at Screening Visit, so please update as ND Not Done for Height and weight. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 08:34:41
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
Query 'Data is required. Please provide.' answered with 'per query information has been updated' (Site from System).	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 23:03:52
Query 'Per CDM : As per CCG Height, Weight, and BMI will only be captured at Screening Visit, so please update as ND Not Done for Height and weight. Thank you' answered with 'per query, information updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 23:03:27
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 23:03:14
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 23:03:14
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 23:03:14
User opened query 'Per CDM : As per CCG Height, Weight, and BMI will only be captured at Screening Visit, so please update as ND Not Done for Height and weight. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:47:47
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:03:27
User entered '158' cm	Mario Portilla (b) (4) (b) (4)	23 Feb 2021 23:05:15
DataPoint set to visible.	System	19 Feb 2021 18:22:03

US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Mar 2021 08:34:43
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
Query 'Data is required. Please provide.' answered with 'per query, information has been updated' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 23:04:12
User opened query 'Data is required. Please provide.' (Site from System).	Mario Portilla (b) (4)	09 Mar 2021 23:03:14
Signature has been broken.	(b) (4)	09 Mar 2021 23:03:14
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4)	09 Mar 2021 23:03:14
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '177' lb	(b) (4)	23 Feb 2021 23:05:15
DataPoint set to visible.	Mario Portilla (b) (4)	19 Feb 2021 18:22:03

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '97.9' F	(b) (4)	23 Feb 2021 23:05:15
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Oral (Oral)'	(b) (4)	23 Feb 2021 23:05:15
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	23 Feb 2021 23:05:15
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '82'	(b) (4)	23 Feb 2021 23:05:15
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Feb 2021 23:05:15

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '16'	(b) (4)	23 Feb 2021 23:05:15
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Feb 2021 23:05:15

US3842040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '120'	(b) (4)	23 Feb 2021 23:05:15
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Feb 2021 23:05:15



**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '70'	(b) (4)	23 Feb 2021 23:05:15
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Feb 2021 23:05:15

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:52
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 23:05:33
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:32:52
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '23 Feb 2021'	(b) (4)	23 Feb 2021 23:05:33
	Mario Portilla (b) (4)	
	(b) (4)	

US3842040

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:32:45

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:34:37
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 23:05:52
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:34:37
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '23 Feb 2021'	(b) (4)	23 Feb 2021 23:05:52
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:05
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:36:17
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:32:31

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:05
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:36:17
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '4 Dec 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:32:31



**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:05
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:36:17
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Clinic (Clinic)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:32:31

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:05
User entered 'SICKD28'	System	10 Dec 2020 14:32:31

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:36
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:33:53

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:36
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '4 Dec 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:33:53

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:36
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '09:59'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:33:53

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
User entered '4 Dec 2020 09:59'	System	10 Dec 2020 14:33:53

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:36
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '97.8' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:33:53

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:36
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Oral (Oral)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:33:53



**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:36
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:33:53

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:36
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '70'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:33:53

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
User entered 'bpm'	System	10 Dec 2020 14:33:53

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:36
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '16'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:33:53

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
User entered 'breaths/min'	System	10 Dec 2020 14:33:53

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:36
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '135'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:33:53

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
User entered 'mmHg'	System	10 Dec 2020 14:33:53

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:36
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '78'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:33:53



US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17
User entered 'mmHg'	System	10 Dec 2020 14:33:53

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:17

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:49
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:34:00

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:38:49
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '4 Dec 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:34:00

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:32:45

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:32
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:39:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:34:20

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:52:32
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:39:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '4 Dec 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 14:34:20

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	19 Feb 2021 18:53:40
	(b) (4)	



**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	19 Feb 2021 18:53:40
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	19 Feb 2021 18:53:40
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	19 Feb 2021 18:53:40

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 16:33:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 16:33:40
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 16:33:40
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 16:33:36
Signature has been broken.	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	19 Feb 2021 18:58:25
	(b) (4)	

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '17 Feb 2021'	Mario Portilla (b) (4)	19 Feb 2021 18:58:25
	(b) (4)	

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '11:50'	Mario Portilla (b) (4)	19 Feb 2021 18:58:25
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 16:33:36
User entered '17 Feb 2021 11:50'	System	19 Feb 2021 18:58:25

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '36.8' C	Mario Portilla (b) (4)	19 Feb 2021 18:58:25
	(b) (4)	



US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'Oral (Oral)'	Mario Portilla (b) (4)	19 Feb 2021 18:58:25
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	19 Feb 2021 18:58:25
	(b) (4)	

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '76'	Mario Portilla (b) (4)	19 Feb 2021 18:58:25
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 16:33:36
User entered 'bpm'	System	19 Feb 2021 18:58:25

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '16'	Mario Portilla (b) (4)	19 Feb 2021 18:58:25
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 16:33:36
User entered 'breaths/min'	System	19 Feb 2021 18:58:25

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '126'	Mario Portilla (b) (4)	19 Feb 2021 18:58:25
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 16:33:36
User entered 'mmHg'	System	19 Feb 2021 18:58:25



US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	27 Apr 2021 16:33:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '76'	Mario Portilla (b) (4)	19 Feb 2021 18:58:25
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 16:33:36
User entered 'mmHg'	System	19 Feb 2021 18:58:25

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	23 Mar 2021 20:57:03
	(b) (4)	

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	23 Mar 2021 20:57:03
	(b) (4)	

US3842040

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 12 Aug 2021 13:32:45**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Mario Portilla (b) (4)	23 Mar 2021 20:57:27
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	23 Mar 2021 20:57:27
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:34
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'No (N)'	(b) (4)	24 Feb 2021 17:44:32
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:34
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:32
	Mario Portilla (b) (4)	
	(b) (4)	



US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:34
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:32
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	24 Feb 2021 17:44:32

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'No (N)'	(b) (4)	24 Feb 2021 17:44:48
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:48
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:48
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 17:44:48

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:48
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:48
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:48
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:48
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 17:44:48

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:48
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 17:44:48

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:48
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 17:44:48

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:48
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 17:44:48

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:36:46
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'No (N)'	(b) (4)	24 Feb 2021 17:44:59
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:32:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:36:46
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:44:59
	Mario Portilla (b) (4)	
	(b) (4)	

US3842040

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:32:45

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:19
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	24 Feb 2021 17:45:08
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 12 Aug 2021 13:32:45**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:19
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	24 Feb 2021 17:45:08
	Mario Portilla (b) (4)	
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:01:47
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:10:55
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:01:47
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '13 Jan 2021'	Zoraida Cruz (b) (4)	13 Jan 2021 22:10:55
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:01:47
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Clinic (Clinic)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:10:55
	(b) (4)	



US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 22:10:55

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:32:45

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:03:24
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '13 Jan 2021'	Zoraida Cruz (b) (4)	13 Jan 2021 22:36:45
	(b) (4)	

**US3842040**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:32:45**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:12:05

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:32:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:03:24
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:36:45
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:32:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:12:05

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:32:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:03:24
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '13 Jan 2021'	Zoraida Cruz (b) (4)	13 Jan 2021 22:36:45
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:32:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:03:24
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Placebo (Placebo)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:36:45
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:32:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:03:24
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:18:20
User entered 'Placebo (Placebo)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:36:45
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:32:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:03:24
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:18:20
User entered 'Placebo (Placebo)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:36:45
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:32:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:03:24
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:36:45
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:32:45

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'I'	System	13 Jan 2021 22:36:45

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'I'	System	13 Jan 2021 22:36:45

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered empty.	System	13 Jan 2021 22:43:43
DataPoint set to visible.	System	13 Jan 2021 22:36:45

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

**US3842040**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:32:45**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered empty.	System	13 Jan 2021 22:43:43
DataPoint set to visible.	System	13 Jan 2021 22:36:45

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User accepted default value 'Pre-Dose (PREDOSE)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '13 Jan 2021'	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '11:51'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered '13 Jan 2021 11:51'	System	13 Jan 2021 22:43:43

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '98.5' F	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Oral (Oral)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '65'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

**US3842040**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'bpm'	System	13 Jan 2021 22:43:43

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '14'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'breaths/min'	System	13 Jan 2021 22:43:43

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '115'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mmHg'	System	13 Jan 2021 22:43:43



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '61'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mmHg'	System	13 Jan 2021 22:43:43

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

**US3842040**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:32:45**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered empty.	System	13 Jan 2021 22:43:43
DataPoint set to visible.	System	13 Jan 2021 22:36:45

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User accepted default value 'Post-Dose (POSTDOSE)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '13 Jan 2021'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Jan 2021 22:47:21
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Jan 2021 22:47:21
User entered '15:05' reason for change: Per Query Resolution	Malithi Desilva (b) (4)	22 Jan 2021 22:47:21
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Jan 2021 22:43:43
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered '13 Jan 2021 15:05'	System	22 Jan 2021 22:47:21
User entered empty.	System	13 Jan 2021 22:43:43

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '98.1' F	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Oral (Oral)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '65'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'bpm'	System	13 Jan 2021 22:43:43

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '14'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'breaths/min'	System	13 Jan 2021 22:43:43

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '123'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mmHg'	System	13 Jan 2021 22:43:43

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:05:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '80'	Zoraida Cruz (b) (4)	13 Jan 2021 22:43:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mmHg'	System	13 Jan 2021 22:43:43

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:06:13
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:45:19
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:06:13
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 22:45:19
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:09:22
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:52:11
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:09:22
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Jan 2021 22:53:12
Query 'Date of Test is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	13 Jan 2021 22:53:12
User closed query 'The Pregnancy date of test is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	13 Jan 2021 22:53:12
User entered '13 Jan 2021' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	13 Jan 2021 22:53:12
	(b) (4)	
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Jan 2021 22:52:11
User opened query 'The Pregnancy date of test is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	13 Jan 2021 22:52:11
User entered '13 Jan 2020'	Zoraida Cruz (b) (4)	13 Jan 2021 22:52:11
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:09:22
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Urine (URINE)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:52:11
	(b) (4)	

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:09:22
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Negative (NEGATIVE)'	Zoraida Cruz (b) (4)	13 Jan 2021 22:52:11
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:09:22
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per CDM: 'Was FSH sample collected' is No, however Collection Date and time has been recorded. Please verify and update. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:35:43
Query 'Per CDM: 'Was FSH sample collected' is No, however Collection Date and time has been recorded. Please verify and update. Thank you' answered with 'reviewed eCRF, FSH not collected, data removed' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	27 Jan 2021 17:09:18
User opened query 'Per CDM: 'Was FSH sample collected' is No, however Collection Date and time has been recorded. Please verify and update. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:00:12
User entered 'No (N)'	Zoraida Cruz (b) (4) (b) (4)	13 Jan 2021 22:52:11

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:09:22
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Malithi Desilva (b) (4)	27 Jan 2021 17:08:54
	(b) (4)	
User entered '13 Jan 2021' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	13 Jan 2021 22:53:12
	(b) (4)	
User entered '13 Jan 2020'	Zoraida Cruz (b) (4)	13 Jan 2021 22:52:11
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:09:22
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Malithi Desilva (b) (4)	27 Jan 2021 17:08:54
	(b) (4)	
User entered '12:57'	Zoraida Cruz (b) (4)	13 Jan 2021 22:52:11
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered empty.	System	27 Jan 2021 17:08:54
User entered '13 Jan 2021 12:57'	System	13 Jan 2021 22:53:12
User entered '13 Jan 2020 12:57'	System	13 Jan 2021 22:52:11

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:00
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	13 Jan 2021 23:05:19
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:00
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 23:05:19
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:00
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	13 Jan 2021 23:05:19
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mRNA-1273'	System	13 Jan 2021 23:05:19
DataPoint set to visible.	System	13 Jan 2021 22:36:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:00
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '13 Jan 2021'	Zoraida Cruz (b) (4)	13 Jan 2021 23:05:19
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:00
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '14:20'	Zoraida Cruz (b) (4)	13 Jan 2021 23:05:19
	(b) (4)	

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered '13 Jan 2021 14:20'	System	13 Jan 2021 23:05:19

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:00
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Zoraida Cruz (b) (4)	13 Jan 2021 23:05:19
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:00
User entered 'ONCE'	System	13 Jan 2021 23:05:19



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 23:05:19

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:35
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	13 Jan 2021 23:05:55
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:35
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '13 Jan 2021'	Zoraida Cruz (b) (4)	13 Jan 2021 23:05:55
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:35
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '12:25'	Zoraida Cruz (b) (4)	13 Jan 2021 23:05:55
	(b) (4)	

**US3842040**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered '13 Jan 2021 12:25'	System	13 Jan 2021 23:05:55

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:32:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:49
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	13 Jan 2021 23:06:14
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:32:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:49
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '13 Jan 2021'	Zoraida Cruz (b) (4)	13 Jan 2021 23:06:14
	(b) (4)	

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:32:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:49
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '12:28'	Zoraida Cruz (b) (4)	13 Jan 2021 23:06:14
	(b) (4)	



**US3842040**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:32:45**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered '13 Jan 2021 12:28'	System	13 Jan 2021 23:06:14

US3842040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:10:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	13 Jan 2021 23:06:59
	(b) (4)	

**US3842040**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'I'	System	13 Jan 2021 23:06:59

**US3842040**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:25:52
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Christie Lyn Costanza	20 Jan 2021 23:09:34
	(b) (4)	

**US3842040**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:25:52
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '20 Jan 2021'	Christie Lyn Costanza	20 Jan 2021 23:09:34
	(b) (4)	

US3842040

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:25:52
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza	20 Jan 2021 23:09:34
	(b) (4)	

**US3842040**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:25:52
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Christie Lyn Costanza	20 Jan 2021 23:09:34
	(b) (4)	

US3842040

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:26:02
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Christie Lyn Costanza	20 Jan 2021 23:09:39
	(b) (4)	



**US3842040**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'I'	System	20 Jan 2021 23:09:39

**US3842040**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'I'	System	20 Jan 2021 23:09:39
DataPoint set to visible.	System	20 Jan 2021 23:09:39

US3842040

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:32:31
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:14:36
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:32:31
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Per response, the Immuno sample was collected on OL-D29 in error and sent to PPD. Please confirm Sample dated 15FEB2021 (1F600530167) is for Unscheduled and update this additional Immuno sample under UNSCH Immunogenicity form in EDC.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 09:43:39
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Per response, the Immuno sample was collected on OL-D29 in error and sent to PPD. Please confirm Sample dated 15FEB2021 (1F600530167) is for Unscheduled and update this additional Immuno sample under UNSCH Immunogenicity form in EDC.' answered with 'OL Day 29: the second dose was administered on that date. If the "once" is triggering this query, then it would be changed to transcription error; however, it is not possible to make any changes on that page. Per the PPD flowsheet, labs were scheduled for collection on OL 29; however, it has been recently clarified that blood labs were not required for OL Day 29 and specimen collection logs did not include a spot for documenting the labs collected on OL Day 29' (Site from DM).	Mario Portilla (b) (4)	03 Mar 2021 21:57:22
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Per response, the Immuno sample was collected on OL-D29 in error and sent to PPD. Please confirm Sample dated 15FEB2021 (1F600530167) is for Unscheduled and update this additional Immuno sample under UNSCH Immunogenicity form in EDC.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 12:08:50

US3842040

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Requery: Please verify if the immune sample details can be updated under OL-D29 as " frequency of dosing"= " once" under exposure form. Thanks ? ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 11:40:19
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Requery: Please verify if the immune sample details can be updated under OL-D29 as " frequency of dosing"= " once" under exposure form. Thanks ? ' answered with 'OL Day 29: the second dose was administered on that date. If the "once" is triggering this query, then it would be changed to transcription error; however, it is not possible to make any changes on that page. Per the PPD flowsheet, labs were scheduled for collection on OL 29; however, it has been recently clarified that blood labs were not required for OL Day 29 and specimen collection logs did not include a spot for documenting the labs collected on OL Day 29' (Site from DM).	Mario Portilla (b) (4) (b) (4)	02 Mar 2021 22:48:18
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Requery: Please verify if the immune sample details can be updated under OL-D29 as " frequency of dosing"= " once" under exposure form. Thanks ? ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:35:07
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:35:07

US3842040

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'OL day 29 does not have a documentation sheet in iMedidata for samples collected on OL Day 29. Additionally, the sample collection log does not have a spot for documenting OL Day 29 sample collection information' (Site from DM).	Mario Portilla (b) (4)	26 Feb 2021 23:31:31
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 10:42:12
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '15 Feb 2021'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 18:14:36

US3842040

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:32:31
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Clinic (Clinic)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:14:36
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'OLD29'	System	15 Feb 2021 18:14:36



US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User accepted default value 'Pre-Dose (PREDOSE)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '15 Feb 2021'	(b) (4)	
	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '12:01'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered '15 Feb 2021 12:01'	System	15 Feb 2021 18:17:01

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '97.4' F	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Oral (Oral)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	



US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '76'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'bpm'	System	15 Feb 2021 18:17:01

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '14'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'breaths/min'	System	15 Feb 2021 18:17:01

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '118'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mmHg'	System	15 Feb 2021 18:17:01

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '76'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mmHg'	System	15 Feb 2021 18:17:01



US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User accepted default value 'Post-Dose (POSTDOSE)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 19:25:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 19:25:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Mario Portilla (b) (4)	15 Feb 2021 19:25:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 18:17:01
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '15 Feb 2021' reason for change: Data Entry Error	Mario Portilla (b) (4)	15 Feb 2021 19:25:41
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '14:14' reason for change: Data Entry Error	Mario Portilla (b) (4)	15 Feb 2021 19:25:41
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered '15 Feb 2021 14:14'	System	15 Feb 2021 19:25:41
User entered empty.	System	15 Feb 2021 18:17:01

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '97.7' F reason for change: Data Entry Error	Mario Portilla (b) (4)	15 Feb 2021 19:25:41
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mario Portilla (b) (4)	15 Feb 2021 19:25:41
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	



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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '65' reason for change: Data Entry Error	Mario Portilla (b) (4)	15 Feb 2021 19:25:41
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'bpm'	System	15 Feb 2021 19:25:41
User entered empty.	System	15 Feb 2021 18:17:01

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '14' reason for change: Data Entry Error	Mario Portilla (b) (4)	15 Feb 2021 19:25:41
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'breaths/min'	System	15 Feb 2021 19:25:41
User entered empty.	System	15 Feb 2021 18:17:01

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '120' reason for change: Data Entry Error	Mario Portilla (b) (4)	15 Feb 2021 19:25:41
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mmHg'	System	15 Feb 2021 19:25:41
User entered empty.	System	15 Feb 2021 18:17:01

US3842040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:33:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '75' reason for change: Data Entry Error	Mario Portilla (b) (4)	15 Feb 2021 19:25:41
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:01
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mmHg'	System	15 Feb 2021 19:25:41
User entered empty.	System	15 Feb 2021 18:17:01



US3842040

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:34:45
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:09
	(b) (4)	

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:34:45
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:09
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:34:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:28
	(b) (4)	

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Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:34:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '15 Feb 2021'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:28
	(b) (4)	

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Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:34:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Urine (URINE)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:28
	(b) (4)	

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**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:34:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:28
	(b) (4)	

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Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:34:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:28
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:34:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:28
	(b) (4)	



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Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:45

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:34:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	15 Feb 2021 18:17:28
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered empty.	System	15 Feb 2021 18:17:28

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:35:55
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	15 Feb 2021 18:57:17
	(b) (4)	

US3842040

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:35:55
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	15 Feb 2021 18:57:17
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:35:55
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	15 Feb 2021 18:57:17
	(b) (4)	

**US3842040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mRNA-1273'	System	15 Feb 2021 18:57:17
DataPoint set to visible.	System	20 Jan 2021 23:09:39

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:35:55
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '15 Feb 2021'	Mario Portilla (b) (4)	15 Feb 2021 18:57:17
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:35:55
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '13:42'	Mario Portilla (b) (4)	15 Feb 2021 18:57:17
	(b) (4)	



**US3842040**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:32:45**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered '15 Feb 2021 13:42'	System	15 Feb 2021 18:57:17

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:35:55
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Mario Portilla (b) (4)	15 Feb 2021 18:57:17
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:35:55
User entered 'ONCE'	System	15 Feb 2021 18:57:17

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'INTRAMUSCULAR'	System	15 Feb 2021 18:57:17

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:36:12
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	15 Feb 2021 19:25:52
	(b) (4)	

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**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'I'	System	15 Feb 2021 19:25:52

**US3842040**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	05 Mar 2021 21:34:42
	(b) (4)	

**US3842040**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered '22 Feb 2021'	Zoraida Cruz (b) (4)	05 Mar 2021 21:34:42
	(b) (4)	



**US3842040**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Zoraida Cruz (b) (4)	05 Mar 2021 21:34:42
	(b) (4)	

**US3842040**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:32:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	05 Mar 2021 21:34:42
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	05 Mar 2021 21:34:49
	(b) (4)	

**US3842040**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:32:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'I'	System	05 Mar 2021 21:34:49

US3842040

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:54:59
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	22 Mar 2021 18:35:46
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:54:59
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '22 Mar 2021'	(b) (4)	
	Malithi Desilva (b) (4)	22 Mar 2021 18:35:46
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:54:59
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User entered 'Clinic (Clinic)'	Malithi Desilva (b) (4)	22 Mar 2021 18:35:46
	(b) (4)	

**US3842040**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:32:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'OLD57'	System	22 Mar 2021 18:35:46



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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:23
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'Yes (Y)'	(b) (4)	
	Malithi Desilva (b) (4)	22 Mar 2021 18:37:37
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:23
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '22 Mar 2021'	(b) (4)	
	Malithi Desilva (b) (4)	22 Mar 2021 18:37:37
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:23
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 19:02:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Mar 2021 19:02:47
User entered '14:35' reason for change: New Information	Malithi Desilva (b) (4)	22 Mar 2021 19:02:47
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 18:37:37
User entered empty.	Malithi Desilva (b) (4)	22 Mar 2021 18:37:37
	(b) (4)	

**US3842040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered '22 Mar 2021 14:35'	System	22 Mar 2021 19:02:47
User entered empty.	System	22 Mar 2021 18:37:37

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:23
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 19:02:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Mar 2021 19:02:47
User entered '98.2' F reason for change: New Information	Malithi Desilva (b) (4)	22 Mar 2021 19:02:47
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 18:37:37
User entered empty.	Malithi Desilva (b) (4)	22 Mar 2021 18:37:37
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:23
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 19:02:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Mar 2021 19:02:53
User entered 'Oral (Oral)' reason for change: New Information	Malithi Desilva (b) (4)	22 Mar 2021 19:02:53
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 19:02:47
User entered empty.	Malithi Desilva (b) (4)	22 Mar 2021 18:37:37
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:23
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	22 Mar 2021 18:37:37
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:23
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 19:02:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Mar 2021 19:02:47
User entered '79' reason for change: New Information	Malithi Desilva (b) (4)	22 Mar 2021 19:02:47
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 18:37:37
User entered empty.	Malithi Desilva (b) (4)	22 Mar 2021 18:37:37
	(b) (4)	



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**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'bpm'	System	22 Mar 2021 19:02:47
User entered empty.	System	22 Mar 2021 18:37:37

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:23
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 19:02:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Mar 2021 19:02:47
User entered '14' reason for change: New Information	Malithi Desilva (b) (4)	22 Mar 2021 19:02:47
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 18:37:37
User entered empty.	Malithi Desilva (b) (4)	22 Mar 2021 18:37:37
	(b) (4)	

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**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'breaths/min'	System	22 Mar 2021 19:02:47
User entered empty.	System	22 Mar 2021 18:37:37

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:23
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 19:02:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Mar 2021 19:02:47
User entered '133' reason for change: New Information	Malithi Desilva (b) (4)	22 Mar 2021 19:02:47
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 18:37:37
User entered empty.	Malithi Desilva (b) (4)	22 Mar 2021 18:37:37
	(b) (4)	

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**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mmHg'	System	22 Mar 2021 19:02:47
User entered empty.	System	22 Mar 2021 18:37:37

US3842040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:23
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 19:02:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Mar 2021 19:02:47
User entered '76' reason for change: New Information	Malithi Desilva (b) (4)	22 Mar 2021 19:02:47
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 18:37:37
User entered empty.	Malithi Desilva (b) (4)	22 Mar 2021 18:37:37
	(b) (4)	

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**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered 'mmHg'	System	22 Mar 2021 19:02:47
User entered empty.	System	22 Mar 2021 18:37:37

**US3842040**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14



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**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:32:45**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:34
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User entered 'No (N)'	Malithi Desilva (b) (4)	22 Mar 2021 18:35:51
	(b) (4)	

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:56:34
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	22 Mar 2021 18:35:51
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:57:22
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	22 Mar 2021 19:09:41
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:57:22
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User entered '22 Mar 2021'	Malithi Desilva (b) (4)	22 Mar 2021 19:09:41
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:57:22
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
User entered '15:00'	Malithi Desilva (b) (4)	22 Mar 2021 19:09:41
	(b) (4)	

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**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:32:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:34:14
User entered '22 Mar 2021 15:00'	System	22 Mar 2021 19:09:41

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:32:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:06:15
User closed query 'Per CDM Re-Query: Site response noted; Kindly provide the AE log-Line number. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 20:34:38
Query 'Per CDM Re-Query: Site response noted; Kindly provide the AE log-Line number. Thank you. ' answered with 'symptoms deactivated were collapsed into AE log line 1 symptomatic Covid-19' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	19 Apr 2021 17:38:40
User opened query 'Per CDM Re-Query: Site response noted; Kindly provide the AE log-Line number. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 06:49:01
User closed query 'Per CDM: Any COVID-19 symptoms should be recorded as symptoms until confirmed COVID-19 diagnosis, and then the COVID-19 diagnosis should be recorded. Collapse the symptoms into the COVID-19 diagnosis. Refer to Protocol 8.3 which includes specific details for all AE Reporting.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 06:48:18
Query 'Per CDM: Any COVID-19 symptoms should be recorded as symptoms until confirmed COVID-19 diagnosis, and then the COVID-19 diagnosis should be recorded. Collapse the symptoms into the COVID-19 diagnosis. Refer to Protocol 8.3 which includes specific details for all AE Reporting.' answered with 'per query, additional information has been added' (Site from DM).	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:58:53
User opened query 'Per CDM: Any COVID-19 symptoms should be recorded as symptoms until confirmed COVID-19 diagnosis, and then the COVID-19 diagnosis should be recorded. Collapse the symptoms into the COVID-19 diagnosis. Refer to Protocol 8.3 which includes specific details for all AE Reporting.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 01:07:41
User signature succeeded.	Shobha Swaminathan (b) (4)	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:07:50
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:01:13



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 22:06:42
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:29:25
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:23:14
User entered 'USA-US110-2020-mRNA-1273-P301000001'	System	05 Nov 2020 16:21:43
User entered 'New'	(b) (4), (b) (6)	05 Nov 2020 16:21:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User closed query 'Per CDM: Site reports subject had Symptomatic Covid-19. Please verify data and update AE term to 'Symptomatic Covid-19' to align with page 7 of v5.0 of CCGs, "AE term should be 'Symptomatic Covid-19' if symptomatic". Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:12:59
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 17:50:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	31 Mar 2021 17:50:21
Data point term sent to Coder	System	31 Mar 2021 17:49:25
Query 'Per CDM: Site reports subject had Symptomatic Covid-19. Please verify data and update AE term to 'Symptomatic Covid-19' to align with page 7 of v5.0 of CCGs, "AE term should be 'Symptomatic Covid-19' if symptomatic". Thank you.' answered with 'reviewed and updated per query' (Site from DM).	Malithi Desilva (b) (4)	31 Mar 2021 17:48:53
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	31 Mar 2021 17:48:34
Coding entries removed.	(b) (4)	
	Malithi Desilva (b) (4)	31 Mar 2021 17:48:34
Signature has been broken.	(b) (4)	
	Malithi Desilva (b) (4)	31 Mar 2021 17:48:34
User entered 'symptomatic COVID-19' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per CDM: Site reports subject had Symptomatic Covid-19. Please verify data and update AE term to 'Symptomatic Covid-19' to align with page 7 of v5.0 of CCGs, "AE term should be 'Symptomatic Covid-19' if symptomatic". Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 00:42:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per CDM: Please consider updating to 'Covid-19'. Thank you.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 13:58:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:45:57
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:18
Data point term sent to Coder	System	23 Nov 2020 17:02:18
Query 'Per CDM: Please consider updating to 'Covid-19'. Thank you.' answered with 'updated per request' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:02:03
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:01:50
Coding entries removed.	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:01:50
User entered 'COVID-19' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:01:50
User opened query 'Per CDM: Please consider updating to 'Covid-19'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 00:21:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 05:00:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 05:00:49
Data point term sent to Coder	System	04 Nov 2020 22:09:10
User entered 'Positive COVID-19 Dx'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:09:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User closed query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 10:44:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' answered with 'Flow Chart and eCRF updated and recorded as an MAAE.' (Site from DM).	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 22:12:33
DataPoint Un-verified.	Zoraida Cruz (b) (4)	15 Feb 2021 22:04:11
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 22:04:11
User opened query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:22:17
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered 'No (N)'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:09:09

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:09:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 20:35:06
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:38:20
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User closed query 'PV Query: Please confirm the start date, since medications were administered for congestion and headache on Nov 1 and Nov 2.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:12:04
Query 'PV Query: Please confirm the start date, since medications were administered for congestion and headache on Nov 1 and Nov 2.' answered with 'confirmed with Illness visit source documentation. Participant reported symptoms starting 29OCT2020, updated start date to onset of symptoms, symptom log updated' (Site from Safety).	Malithi Desilva (b) (4)	04 Jan 2021 18:47:17
	(b) (4)	
DataPoint Un-verified.	Malithi Desilva (b) (4)	04 Jan 2021 18:47:02
	(b) (4)	
User entered '29 Oct 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4)	04 Jan 2021 18:47:02
	(b) (4)	
User opened query 'PV Query: Please confirm the start date, since medications were administered for congestion and headache on Nov 1 and Nov 2.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 17:33:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered '3 Nov 2020'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:38:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:09:09

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 17:45:12
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	
	Malithi Desilva (b) (4)	10 Dec 2020 17:45:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 20:35:06
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:03:52
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Dec 2020 17:45:12
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 Dec 2020 17:45:12
DataPoint Un-verified.	Malithi Desilva (b) (4)	10 Dec 2020 17:45:12
	(b) (4)	
User entered '4 Dec 2020' reason for change: Per Query Resolution	Malithi Desilva (b) (4)	10 Dec 2020 17:45:12
	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Dec 2020 17:43:47
User closed query 'PV Query: Please provide the event end date, when available (when symptoms resolved).' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:12:52
Query 'PV Query: Please provide the event end date, when available (when symptoms resolved).' answered with 'Pending 12/04/2020 Illness visit day 28' (Site from Safety).	Mario Portilla (b) (4)	01 Dec 2020 22:58:15
	(b) (4)	
User opened query 'PV Query: Please provide the event end date, when available (when symptoms resolved).' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:42:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:04:48
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User closed query 'PV Query: Please provide the event end date, when available (when symptoms resolved).' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 13:59:20
Query 'PV Query: Please provide the event end date, when available (when symptoms resolved).' answered with 'event end date provided ' (Site from Safety).	Malithi Desilva (b) (4)	10 Dec 2020 17:45:29
	(b) (4)	
User opened query 'PV Query: Please provide the event end date, when available (when symptoms resolved).' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:45:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:09:09

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:39:07
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 22:09:09

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:36:20
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered '0'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:37:40
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered '0'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:37:09
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered '0'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:05:06
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:05:30
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:05:47
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:06:19
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:36:04
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered '0'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:35:08
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered '0'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:37:58
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered '0'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:54:10
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:11:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 22:11:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	04 Nov 2020 22:11:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:09:09
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:11:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 22:11:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	04 Nov 2020 22:11:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:09:09
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:38:52
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User closed query 'PV Query: As the last dose of study drug was given on 16 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 15:23:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:46:02
Query 'PV Query: As the last dose of study drug was given on 16 Oct 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated per query request' (Site from Safety).	Malithi Desilva (b) (4)	23 Nov 2020 17:02:47
	(b) (4)	
DataPoint Un-verified.	Malithi Desilva (b) (4)	23 Nov 2020 17:02:22
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	23 Nov 2020 17:02:22
	(b) (4)	
User opened query 'PV Query: As the last dose of study drug was given on 16 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:42:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:12:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 22:12:05
User entered 'None (NONE)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	04 Nov 2020 22:12:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:09:09
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

None

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Apr 2021 00:57:38
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	28 Apr 2021 20:20:20
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	25 Mar 2021 21:54:22
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	23 Mar 2021 15:26:43
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered '0' reason for change: Data Entry Error	Malithi Desilva (b) (4)	05 Nov 2020 15:40:04
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Nov 2020 22:12:05
User entered '1' reason for change: Data Entry Error	Malithi Desilva (b) (4)	04 Nov 2020 22:12:05
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Nov 2020 22:09:09
User entered '0'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:03:10
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
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.	(b) (4), (b) (6)	13 Jan 2021 09:14:39
' (Site from DM).		
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.	Malithi Desilva (b) (4)	04 Jan 2021 18:49:20
	(b) (4)	
' answered with 'Participant reported taking multiple medications for covid19 symptoms within the timeframe dated here. Each symptom was added as an AE. Please advise further on how to proceed with documentation.' (Site from DM).		
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.	(b) (4), (b) (6)	28 Dec 2020 01:20:04
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered '1' reason for change: Data Entry Error	Malithi Desilva (b) (4)	05 Nov 2020 15:40:04
	(b) (4)	
User entered '0'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:03:26
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered '0'	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:35:06
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:39:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query ' PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 13:59:32
Query ' PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'event outcome updated ' (Site from Safety).	Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 17:44:08
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 17:43:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	10 Dec 2020 17:43:47
User opened query ' PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:45:49
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:12:58
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Day 28 Illness visit upcoming 12/04/2020 ' (Site from Safety).	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 22:57:40



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:45

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:42:52
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:09:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 22:09:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	04 Nov 2020 22:09:52
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:09:09
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:07:04
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 22:07:29
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User closed query 'PV Query: Please provide the symptoms reported by the subject that started on 29 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 01:44:16
Query 'PV Query: Please provide the symptoms reported by the subject that started on 29 Oct 2020.' answered with 'participant reported sore throat and cough began 29OCT2020' (Site from Safety).	Malithi Desilva (b) (4)	22 Jan 2021 22:55:04
	(b) (4)	
User opened query 'PV Query: Please provide the symptoms reported by the subject that started on 29 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 17:13:02
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:13:07
User closed query 'PV Query: Please provide day 1 (03 Nov 2020) of the COVID-19 symptom log.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:13:06
User closed query 'PV Query: Please confirm if joint pain and right knee pain listed in concomitant medication indications should be added as medical history.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:13:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No medical or surgical treatments administered thus far. concomitant medications listed in eCRF' (Site from Safety). DataPoint Un-verified.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 22:34:30
User entered 'medications listed in concomitant medications list per protocol' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 22:32:02
Query 'PV Query: Please confirm if joint pain and right knee pain listed in concomitant medication indications should be added as medical history.' answered with 'Osteoarthritis in right knee condition updated in medical history (confirmed with source document medical history flowsheet). Osteoarthritis the condition for joint pain and right knee indications.' (Site from Safety).	Malithi Desilva (b) (4) (b) (4)	01 Dec 2020 18:48:29
Query 'PV Query: Please provide day 1 (03 Nov 2020) of the COVID-19 symptom log.' answered with 'Day 1 (03NOV2020) entered into symptom log, see Row 7.' (Site from Safety).	Malithi Desilva (b) (4) (b) (4)	01 Dec 2020 18:30:04
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:43:11
User opened query 'PV Query: Please provide day 1 (03 Nov 2020) of the COVID-19 symptom log.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:41:53

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if joint pain and right knee pain listed in concomitant medication indications should be added as medical history.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:41:38
	(b) (4), (b) (6)	10 Nov 2020 21:29:25
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 22:09:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 22:09:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Feb 2021 22:04:11
User entered '0'	System	04 Nov 2020 22:09:09

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 02:53:53



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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac disorders, signs and symptoms NEC, HLT: Cardiac signs and symptoms NEC, PT: Palpitations, LLT: Palpitation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Dec 2020 23:03:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Dec 2020 23:03:52
Data point term sent to Coder	System	01 Dec 2020 23:03:09
User entered 'PALPITATION'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per sponsor review, please review and update field as Palpitations are not a solicited symptom from patient e-dairy. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 08:08:54
Query 'Per sponsor review, please review and update field as Palpitations are not a solicited symptom from patient e-dairy. ' answered with 'updated per query' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:39:49
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:39:38
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:39:38
User opened query 'Per sponsor review, please review and update field as Palpitations are not a solicited symptom from patient e-dairy. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 20:56:13
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User closed query 'PV Query: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 02:53:47
Query 'PV Query: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' answered with 'data update completed' (Site from Safety).	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:16:17
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:16:02
User opened query 'PV Query: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 18:52:33
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '01 Nov 2020'	Mario Portilla (b) (4)	01 Dec 2020 23:03:00
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User entered empty.	System	01 Dec 2020 23:03:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 10:45:07
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'Palpitations have resolved; updated flow sheet and eCRF ' (Site from DM).	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 20:57:12
DataPoint Un-verified.	Zoraida Cruz (b) (4)	15 Feb 2021 20:54:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 20:54:55
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 07:35:48
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00



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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 20:54:55
User entered '15 Dec 2020' reason for change: Per Query Resolution	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 20:54:55
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User entered empty.	System	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	04 Dec 2020 20:54:47
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 23:03:00
	Mario Portilla (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00



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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:03:00
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:03:00
	(b) (4)	

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**Folder: Adverse Events**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	01 Dec 2020 23:03:00
	(b) (4)	



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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	01 Dec 2020 23:03:00
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#2 has a start date 01 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Dec 2020 06:49:12
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#2 has a start date 01 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' answered with 'confirmed with eCRF, updated per query ' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:11:18
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:11:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:11:01
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#2 has a start date 01 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:46:04
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'None (NONE)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'l'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:03:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 20:54:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 20:54:55
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[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 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:03:00



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User entered '0'	System	01 Dec 2020 23:03:00

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59
User entered '0'	System	01 Dec 2020 23:03:00

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:59

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 02:53:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:32:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Pneumonia viral, LLT: Viral pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Dec 2020 23:10:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Dec 2020 23:10:52
Data point term sent to Coder	System	01 Dec 2020 23:10:13
User entered 'VIRAL PNEUMONIA'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:32:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per sponsor review, please review and update field as Viral Pneumonia is not a solicited symptom from patient e-dairy. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 08:11:35
Query 'Per sponsor review, please review and update field as Viral Pneumonia is not a solicited symptom from patient e-dairy. ' answered with 'updated per query' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:40:30
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:40:21
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:40:21
User opened query 'Per sponsor review, please review and update field as Viral Pneumonia is not a solicited symptom from patient e-dairy. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 20:56:29
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:32:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User closed query 'PV Query: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 02:52:46
Query 'PV Query: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' answered with 'data correction made' (Site from Safety).	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:18:26
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:17:11
User opened query 'PV Query: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 18:52:45
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '10 Nov 2020'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User entered empty.	System	01 Dec 2020 23:09:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	15 Feb 2021 21:53:17
DataPoint Un-verified.	System	15 Feb 2021 21:53:17
User entered 'No (N)' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	15 Feb 2021 21:53:17
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Zoraida Cruz (b) (4)	15 Feb 2021 21:53:17
DataPoint Verified.	(b) (4)	15 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 20:54:47
	Mario Portilla (b) (4)	01 Dec 2020 23:09:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User closed query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 10:45:14
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Query 'Per MM, please provide the end date.' answered with 'updated with an end date 15DEC2020' (Site from DM).	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 21:53:43
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	15 Feb 2021 21:53:01
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	15 Feb 2021 21:53:01
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	15 Feb 2021 21:52:50
DataPoint Un-verified.	Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 21:52:50
User entered '15 Dec 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 21:52:50
User opened query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 10:31:15
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User entered empty.	System	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	04 Dec 2020 20:54:47
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 23:09:33
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:32:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:09:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	04 Dec 2020 20:54:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Dec 2020 23:09:33
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:32:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
DataPoint Un-verified.	(b) (4) Mario Portilla (b) (4)	16 Mar 2021 21:47:39
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	16 Mar 2021 21:47:39
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mario Portilla (b) (4)	16 Mar 2021 21:47:39
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	01 Dec 2020 23:09:33
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:32:45

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#3 has a start date 10 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Dec 2020 06:49:37
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#3 has a start date 10 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' answered with 'confirmed with CRF, updated per query resolution ' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:12:12
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:11:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:11:53
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#3 has a start date 10 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:46:25
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 23:26:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 23:26:42
User entered 'None (NONE)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:26:42
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 23:09:33

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**Folder: Adverse Events**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4) (b) (4) (b) (4)	01 Dec 2020 23:09:33

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Folder: Adverse Events

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Generated On: 12 Aug 2021 13:32:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	17 Feb 2021 22:36:37
DataPoint Un-verified.	Zoraida Cruz (b) (4)	17 Feb 2021 22:36:37
Signature has been broken.	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:36:37
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:36:37
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	
User signature succeeded.	System	17 Feb 2021 22:36:16
	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '1'	(b) (4)	
	Mario Portilla (b) (4)	01 Dec 2020 23:09:33
	(b) (4)	



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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
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 10:20:51
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 'Con Med log #22 methyl prednisone therapy was administered from 11/10/2020 to 11/15/2020' (Site from DM).	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:49:27
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), (b) (6)	14 Mar 2021 03:07:36
User signature succeeded.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
DataPoint Un-verified.	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 22:36:16
Signature has been broken.	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 22:36:16
User entered '1' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 22:36:16
User signature succeeded.	Shobha Swaminathan (b) (4)	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	04 Dec 2020 20:54:47
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 23:09:33
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) Zoraida Cruz (b) (4)	15 Feb 2021 21:53:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 21:53:01
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

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[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 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:09:33

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User entered '0'	System	01 Dec 2020 23:09:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09
User entered '1'	System	01 Dec 2020 23:09:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:09



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 02:53:31

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Acid Reflux. Please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 10:21:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:17:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:17:49
Data point term sent to Coder	System	16 Mar 2021 21:46:50
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Acid Reflux. Please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'per query, information has been updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:46:39
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:46:23
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:46:23
User entered 'worsening INTERMITTENT HEART BURN' reason for change: Per Query Resolution	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:46:23
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Acid Reflux. Please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 03:07:57
User signature succeeded.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 01:03:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 01:03:04

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EAB) (1725)

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Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	17 Feb 2021 22:40:32
DataPoint Un-verified.	Zoraida Cruz (b) (4)	17 Feb 2021 22:39:44
	(b) (4)	
Coding entries removed.	Zoraida Cruz (b) (4)	17 Feb 2021 22:39:44
	(b) (4)	
Signature has been broken.	Zoraida Cruz (b) (4)	17 Feb 2021 22:39:44
	(b) (4)	
User entered 'INTERMITTENT HEART BURN'	Zoraida Cruz (b) (4)	17 Feb 2021 22:39:44
reason for change: Per Query Resolution	(b) (4)	
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 23:27:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 23:27:58
	(b) (4)	
Data point term sent to Coder	System	01 Dec 2020 23:26:25
User entered 'HEART BURN'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:25:35

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Folder: Adverse Events

Form: Adverse Events (4)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per sponsor review, please review and update field as Heart Burn is not a solicited symptom from patient e-dairy. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 08:11:56
Query 'Per sponsor review, please review and update field as Heart Burn is not a solicited symptom from patient e-dairy. ' answered with 'updated per query' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:40:10
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:40:01
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	04 Jan 2021 18:40:01
User opened query 'Per sponsor review, please review and update field as Heart Burn is not a solicited symptom from patient e-dairy. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 20:56:39
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:25:35

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Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User closed query 'PV Query: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 02:53:26
Query 'PV Query: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' answered with 'completed data update' (Site from Safety).	Mario Portilla (b) (4)	03 Dec 2020 19:19:20
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	03 Dec 2020 19:19:01
	(b) (4)	
User opened query 'PV Query: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 18:52:54
User entered 'Yes (Y)'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '14 Nov 2020'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 23:25:35

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[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Site response noted; however, AE term does not reflect "Intermittent" as per previous query response. Please review and reconcile, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:10:22
Query 'Per CDM Re-Query: Site response noted; however, AE term does not reflect "Intermittent" as per previous query response. Please review and reconcile, else clarify. Thank you.' answered with 'AE TERM UPDATED AND CONTINUING' (Site from DM).	Zoraida Cruz (b) (4)	17 Feb 2021 22:41:01
User opened query 'Per CDM Re-Query: Site response noted; however, AE term does not reflect "Intermittent" as per previous query response. Please review and reconcile, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 10:46:31
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 10:46:31
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'AE has been updated to Intermittent Heartburn per participant reports ongoing.' (Site from DM).	Zoraida Cruz (b) (4)	15 Feb 2021 20:53:21
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 07:36:11

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**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Yes (Y)'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Form: Adverse Events (4)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 23:25:35

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**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'No (N)'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:32:45

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
Signature has been broken.	(b) (4) Zoraida Cruz (b) (4)	17 Feb 2021 22:39:44
User entered 'None (NONE)' reason for change: Per Query Resolution	(b) (4) Zoraida Cruz (b) (4)	17 Feb 2021 22:39:44
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#4 has a start date 14 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Dec 2020 06:48:19
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#4 has a start date 14 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' answered with 'confirmed with CRF, updated per query ' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:12:38
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:12:25
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:12:25
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#4 has a start date 14 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:46:46
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'None (NONE)'	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 23:25:35

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'I'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:32:45

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
DataPoint Un-verified.	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 21:46:23
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	16 Mar 2021 21:46:23
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Mario Portilla (b) (4)	16 Mar 2021 21:46:23
User signature succeeded.	(b) (4)	
	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4)	01 Dec 2020 23:25:35
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 23:25:35

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 23:25:35

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:32:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:50
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 19:23:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 19:23:36
Data point term sent to Coder	System	03 Dec 2020 19:22:38
User entered 'vertigo'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:51
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:53
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:54
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:55
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '23 Oct 2020'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:59
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
User entered empty.	System	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:54:57
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:00
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '24 Oct 2020'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:02
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
User entered empty.	System	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:03
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:05
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:06
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

US3842040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:32:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:07
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:11
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

US3842040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:32:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:13
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

US3842040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:32:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:18
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:21
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:22
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:24
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:32:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:25
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Related (RELATED)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:27
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Related (RELATED)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:32:45

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#5 has a start date 23 Oct 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 11:42:25
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#5 has a start date 23 Oct 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' answered with 'confirmed with CRF, updated per query' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:13:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 19:13:12
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 16 Oct 2020 and AE#5 has a start date 23 Oct 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:47:12
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 20:55:29
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'None (NONE)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:32:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:31
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Dec 2020 19:22:39
User entered '1' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:39
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Dec 2020 19:22:19
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:32:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:32
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:37
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:35
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[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 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:34
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:55:38
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:54:47
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
User entered '0'	System	03 Dec 2020 19:22:19

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23
User entered '0'	System	03 Dec 2020 19:22:19



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:23

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Ocular infections, inflammations and associated manifestations, PT: Ocular hyperaemia, LLT: Eye redness - version MedDRA\\23.0.	(b) (4)	09 Feb 2021 23:33:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 23:33:56
Data point term sent to Coder	(b) (4)	09 Feb 2021 23:33:00
User entered 'Right Eye Redness'	System	09 Feb 2021 23:32:45
	Malithi Desilva (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '29 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
User entered empty.	System	09 Feb 2021 23:32:45

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:35:06
Signature has been broken.	Christie Lyn Costanza	26 Apr 2021 20:29:32
User entered '03 Dec 2020' reason for change: Data Entry Error	(b) (4) Christie Lyn Costanza	26 Apr 2021 20:29:32
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '30 Dec 2020'	(b) (4) Malithi Desilva (b) (4)	09 Feb 2021 23:32:45
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
User entered empty.	System	09 Feb 2021 23:32:45

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Malithi Desilva (b) (4)	09 Feb 2021 23:32:45
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:32:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 23:33:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:33:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Malithi Desilva (b) (4)	09 Feb 2021 23:33:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	09 Feb 2021 23:32:45
	Malithi Desilva (b) (4)	09 Feb 2021 23:32:45
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[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 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
User entered '0'	System	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33
User entered '0'	System	09 Feb 2021 23:32:45

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:32:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Apr 2021 00:57:38
	(b) (4)	
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 20:28:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 20:28:18
Data point term sent to Coder	System	28 Apr 2021 20:18:24
DataPoint Un-verified.	Mario Portilla (b) (4)	28 Apr 2021 20:17:36
	(b) (4)	
Coding entries removed.	Mario Portilla (b) (4)	28 Apr 2021 20:17:36
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	28 Apr 2021 20:17:36
	(b) (4)	
User entered 'Cardiac MURMUR' reason for change: Data Entry Error	Mario Portilla (b) (4)	28 Apr 2021 20:17:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 23:36:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 23:36:40
Data point term sent to Coder	System	09 Feb 2021 23:36:04
User entered 'Heart Murmur'	Malithi Desilva (b) (4)	09 Feb 2021 23:35:39
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '14 Dec 2020'	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Apr 2021 00:57:38
	(b) (4)	
DataPoint Un-verified.	Mario Portilla (b) (4)	28 Apr 2021 20:18:02
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	28 Apr 2021 20:18:02
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Mario Portilla (b) (4)	28 Apr 2021 20:18:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'No (N)'	Malithi Desilva (b) (4)	09 Feb 2021 23:35:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Apr 2021 00:57:38
	(b) (4)	
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Apr 2021 20:18:02
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Apr 2021 20:17:36
DataPoint Un-verified.	Mario Portilla (b) (4)	28 Apr 2021 20:17:36
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	28 Apr 2021 20:17:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4)	28 Apr 2021 20:17:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '31 Dec 2020'	Malithi Desilva (b) (4)	09 Feb 2021 23:35:39
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 23:35:39



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'I'	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:32:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Apr 2021 00:57:38
	(b) (4)	
DataPoint Un-verified.	Mario Portilla (b) (4)	28 Apr 2021 20:17:36
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	28 Apr 2021 20:17:36
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Mario Portilla (b) (4)	28 Apr 2021 20:17:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:36:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:36:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	09 Feb 2021 23:36:19
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:35:39
User entered empty.	Malithi Desilva (b) (4)	09 Feb 2021 23:35:39
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:35:39
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 23:35:39

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 23:35:39

US3842040

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:32:45

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 23:39:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 23:39:40
Data point term sent to Coder	System	09 Feb 2021 23:39:06
User entered 'Tinnitus'	Malithi Desilva (b) (4)	09 Feb 2021 23:38:08
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '24 Jan 2021'	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Related (RELATED)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:38:08



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'None (NONE)'	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'I'	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Feb 2021 23:38:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:32:45

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 23:38:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:38:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Malithi Desilva (b) (4)	09 Feb 2021 23:38:18
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:38:08
User entered empty.	Malithi Desilva (b) (4)	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered empty.	(b) (4)	09 Feb 2021 23:38:08
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 23:38:08



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 23:38:08

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 12 Aug 2021 13:32:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:35:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Influenza like illness, LLT: Flu-like symptoms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:10:51
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 09:10:51
Data point term sent to Coder	System	31 Mar 2021 22:34:22
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:33:47
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:33:47
User entered 'Flu-like symptoms: For AE # 20. Plan: will inactivate AE 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, and 32 (unless some of these AE have already been deactivated) per narrative below' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:33:47
User signature succeeded.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 23:35:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 23:35:16
Data point term sent to Coder	System	17 Feb 2021 23:34:16
User entered 'RUNNY NOSE'	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'Yes (Y)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

US3842040

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 12 Aug 2021 13:32:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Runny Nose is not a solicited event for this study. Please review and update response to NO as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 10:48:30
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Runny Nose is not a solicited event for this study. Please review and update response to NO as appropriate. Otherwise, clarify.' answered with 'pre query, information has been updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:15:01
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:14:44
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:14:44
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Runny Nose is not a solicited event for this study. Please review and update response to NO as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 03:36:30
User signature succeeded.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'No (N)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '16 Feb 2021'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Feb 2021 23:34:34
User entered '12:30' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	17 Feb 2021 23:34:34
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Feb 2021 23:33:53
User entered empty.	System	17 Feb 2021 23:33:53
	Zoraida Cruz (b) (4)	17 Feb 2021 23:33:53
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
User entered '16 Feb 2021 12:30'	System	17 Feb 2021 23:34:34
User entered empty.	System	17 Feb 2021 23:33:53

US3842040

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
Signature has been broken.	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 16:59:33
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	08 Mar 2021 16:59:33
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	17 Feb 2021 23:33:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
Signature has been broken.	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 16:59:33
	(b) (4)	
User entered '08 Mar 2021' reason for change: Data Entry Error	Mario Portilla (b) (4)	08 Mar 2021 16:59:33
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	17 Feb 2021 23:33:53
	(b) (4)	

US3842040

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 12 Aug 2021 13:32:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Mar 2021 19:38:29
Signature has been broken.	System	08 Mar 2021 19:38:29
	Mario Portilla (b) (4)	08 Mar 2021 19:38:29
	(b) (4)	
User entered '10:00' reason for change: Per Query Resolution	Mario Portilla (b) (4)	08 Mar 2021 19:38:29
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 16:59:33
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	17 Feb 2021 23:33:53
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
User entered '08 Mar 2021 10:00'	System	08 Mar 2021 19:38:29
User entered empty.	System	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

US3842040

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 12 Aug 2021 13:32:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 23:34:34
User entered 'No (N)' reason for change: Data Entry Error	System	17 Feb 2021 23:34:34
User opened query 'Data is required. Please complete.' (Site from System).	Zoraida Cruz (b) (4)	17 Feb 2021 23:34:34
User entered empty.	(b) (4)	
	System	17 Feb 2021 23:33:53
	Zoraida Cruz (b) (4)	17 Feb 2021 23:33:53
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'Related (RELATED)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'Not Related (NOT RELATED)'	(b) (4)	
reason for change: Data Entry Error	Zoraida Cruz (b) (4)	17 Feb 2021 23:50:47
User entered 'Related (RELATED)'	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 23:33:53
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'None (NONE)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 12 Aug 2021 13:32:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
Signature has been broken.	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 21:19:36
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mario Portilla (b) (4)	16 Mar 2021 21:19:36
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	17 Feb 2021 23:33:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 12 Aug 2021 13:32:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
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) (4), (b) (6)	19 Mar 2021 10:48:38
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 'Participant did not report taking any medications for runny nose; however, she did report conmeds #31 and #32 that are indicated for multiple symptoms' (Site from DM).	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:21:44
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:19:36
User entered '0' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 21:19:36
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), (b) (6)	14 Mar 2021 03:36:41
User signature succeeded.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
User entered '1'	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 12 Aug 2021 13:32:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
Signature has been broken.	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 16:59:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mario Portilla (b) (4)	08 Mar 2021 16:59:33
Data Entry Error	(b) (4)	
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Zoraida Cruz (b) (4)	17 Feb 2021 23:33:53
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[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 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 12 Aug 2021 13:32:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:35:06
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:23:31
User entered 'Per query, AE # 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31 and 32 have overlapping start/end dates. Per query request, these AE symptoms will be combined into one medical condition or diagnosis: Flu-like symptoms. COVID NP collected on 2/23/2021 resulted negative' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:23:31
User signature succeeded.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
User entered '0'	System	17 Feb 2021 23:34:34

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56
User entered '1'	System	17 Feb 2021 23:33:53

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:48:56

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 12 Aug 2021 13:32:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:35:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:36:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:36:00
Data point term sent to Coder	System	08 Apr 2021 16:34:38
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:33:46
Query 'CDM Coding: Please verify the verbatim "CONFIRMED COVID BY NP SWAB COLLECTED ON 11/03/2020 "NAUSEA" THIS AE WILL BE DEACTIVATED" and report only the AE. Else, please clarify "NAUSEA" THIS AE WILL BE DEACTIVATED" statement.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:33:44
' canceled (Site from System).		
Data point term sent to Coder	System	08 Apr 2021 16:32:33
User entered 'NAUSEA' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	08 Apr 2021 16:32:06
User opened query 'CDM Coding: Please verify the verbatim "CONFIRMED COVID BY NP SWAB COLLECTED ON 11/03/2020 "NAUSEA" THIS AE WILL BE DEACTIVATED" and report only the AE. Else, please clarify "NAUSEA" THIS AE WILL BE DEACTIVATED" statement.	Coder Import (b) (4) (b) (4)	08 Apr 2021 03:16:41
' (Site from System).		
Data point term sent to Coder	System	31 Mar 2021 22:57:39
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:57:17

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 12 Aug 2021 13:32:45

[Adverse event](#)

Audit	User	Time (GMT)
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:57:17
User entered 'Confirmed Covid by NP swab collected on 11/03/2020 "NAUSEA" This AE will be deactivated' reason for change: Data Entry Error User signature succeeded.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:57:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 00:08:09
Data point term sent to Coder	Coder Import (b) (4) (b) (4)	24 Feb 2021 00:08:09
User entered 'Nausea'	System Mario Portilla (b) (4) (b) (4)	24 Feb 2021 00:06:59 24 Feb 2021 00:06:54



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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

US3842040

Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 12 Aug 2021 13:32:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
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)	25 Mar 2021 11:10:37
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
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 'per query, information updated' (Site from DM).	(b) (4) Mario Portilla (b) (4) (b) (4)	23 Mar 2021 15:02:22
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	23 Mar 2021 15:01:56
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	23 Mar 2021 15:01:56
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)	22 Mar 2021 05:15:15
User signature succeeded.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	24 Feb 2021 00:06:54

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Folder: Adverse Events

Form: Adverse Events (34)

Generated On: 12 Aug 2021 13:32:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:35:06
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	08 Apr 2021 16:32:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	08 Apr 2021 16:32:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User closed query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 01:46:10
Query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' answered with 'updated per query' (Site from Safety).	Mario Portilla (b) (4) (b) (4)	26 Feb 2021 23:26:59
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	26 Feb 2021 23:26:48
User opened query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:02:01
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	24 Feb 2021 00:06:54

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '9 Nov 2020'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
User entered empty.	System	24 Feb 2021 00:06:54

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '16 Nov 2020'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
User entered empty.	System	24 Feb 2021 00:06:54

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'None (NONE)'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'l'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mario Portilla (b) (4) (b) (4)	24 Feb 2021 00:06:54

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[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 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	24 Feb 2021 00:06:54
	(b) (4)	

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Folder: Adverse Events

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Generated On: 12 Aug 2021 13:32:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:35:06
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:57:17
User entered 'Confirmed Covid by NP swab collected on 11/03/2020 "NAUSEA" This AE will be deactivated' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:57:17
User signature succeeded.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
User entered empty.	Mario Portilla (b) (4) (b) (4)	24 Feb 2021 00:06:54

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
User entered '0'	System	24 Feb 2021 00:06:54



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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10
User entered '0'	System	24 Feb 2021 00:06:54

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**Folder: Adverse Events**

**Form: Adverse Events (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:10

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**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59

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Folder: Adverse Events

Form: Adverse Events (36)

Generated On: 12 Aug 2021 13:32:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:50:40
	(b) (4), (b) (6)	26 Apr 2021 20:35:06
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'On 10/16/2020: Participant here in clinic for visit 2, Day 29 for MODERNA The Cove Study; Was administered 2nd dose of product. This AE was reported 3 days after dose #2 administration and is actually an AR' (Site from DM).	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 22:45:48
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 14:19:25
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:55:23
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:30:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:30:49
Data point term sent to Coder	System	08 Mar 2021 23:30:19
User entered 'Body aches'	Mario Portilla (b) (4) (b) (4)	08 Mar 2021 23:29:52

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**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '19 Oct 2020'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered empty.	(b) (4)	08 Mar 2021 23:29:52
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
User entered empty.	System	08 Mar 2021 23:29:52

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '22 Oct 2020'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered empty.	(b) (4)	08 Mar 2021 23:29:52
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
User entered empty.	System	08 Mar 2021 23:29:52

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mario Portilla (b) (4) (b) (4)	08 Mar 2021 23:29:52

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	



**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'Related (RELATED)'	(b) (4) Mario Portilla (b) (4) (b) (4)	08 Mar 2021 23:29:52

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'None (NONE)'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'l'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mario Portilla (b) (4) (b) (4)	08 Mar 2021 23:29:52

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**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:06
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:55:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	08 Mar 2021 23:29:52
	(b) (4)	

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
User entered '0'	System	08 Mar 2021 23:29:52

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59
User entered '0'	System	08 Mar 2021 23:29:52

**US3842040**

**Folder: Adverse Events**

**Form: Adverse Events (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:44:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:32:45

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:06:15
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 10:51:14
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'tylenol 650mg listed for headaches started prior to day 1' (Site from DM).	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 22:26:33
User closed query 'Per CDM: Please fill in the Concomitant Procedure Summary form according to page 41 of CCGs version 2.0. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:33:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:30
Query 'Per CDM: Please fill in the Concomitant Procedure Summary form according to page 41 of CCGs version 2.0. Thank you.' answered with 'concomitant procedure summary updated' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:25:42
User opened query 'Per CDM: Please fill in the Concomitant Procedure Summary form according to page 41 of CCGs version 2.0. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:49:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:32:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 16:19:16
	(b) (4), (b) (6)	23 Sep 2020 14:44:00



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
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, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:16:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:16:39
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 19:16:10
Coding entries removed.	Malithi Desilva (b) (4)	10 Nov 2020 19:15:18
	(b) (4)	
User entered 'SYMBiCORT' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 19:15:18
	(b) (4)	
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, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 15:31:33
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 15:31:33
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 14:46:39
User entered 'symbacort'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'asthma'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	08 Mar 2021 23:40:42
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '80/4.5' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 19:18:14
	(b) (4)	
User entered '2'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 160/4.5 ug, 80/4.5 ug, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 08:32:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 160/4.5 ug, 80/4.5 ug, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'dose updated' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:20:46
User entered 'ug (ug)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:18:14
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 160/4.5 ug, 80/4.5 ug, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:10:57
User entered 'puff (PUFF)'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:46:40
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:45:53



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '01 Jan 2020'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 14:45:53



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 14:45:53

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 14:45:53

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:48:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:48:38
Data point term sent to Coder	System	23 Sep 2020 14:47:43
User entered 'albuterol'	(b) (4), (b) (6)	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'asthma'	(b) (4), (b) (6)	23 Sep 2020 14:46:44

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
DataPoint Un-verified.	Mario Portilla (b) (4)	01 Dec 2020 21:42:38
	(b) (4)	
User entered '90' reason for change: Data Entry Error	Mario Portilla (b) (4)	01 Dec 2020 21:42:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '2'	(b) (4), (b) (6)	23 Sep 2020 14:46:44

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
DataPoint Un-verified.	Mario Portilla (b) (4)	01 Dec 2020 21:42:38
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Mario Portilla (b) (4)	01 Dec 2020 21:42:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'puff (PUFF)'	(b) (4), (b) (6)	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:46:44



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:46:44

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 14:43:07
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2015). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'corrected start year of asthma to 1986' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	06 Nov 2020 23:42:33
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:11:47
User entered 'un UNK 1986'	(b) (4), (b) (6)	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:46:44



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 14:47:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 14:47:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:47:04
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 14:46:44
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 14:46:44

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 14:46:44

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:53:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:53:36
Data point term sent to Coder	System	23 Sep 2020 14:53:05
User entered 'Tylenol'	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:52:47

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
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. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 12:30:17
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)	13 Nov 2020 12:30:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'occasional tension headaches'	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '650'	(b) (4), (b) (6)	23 Sep 2020 14:52:47



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'un UNK 1979'	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:52:47



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 21:56:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 21:56:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:52:47

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 21:56:07
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 21:56:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User entered empty.	System	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User entered empty.	System	23 Sep 2020 14:52:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:04
User entered empty.	System	23 Sep 2020 14:52:47

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:54:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:54:36
Data point term sent to Coder	System	23 Sep 2020 14:54:06
User entered 'norvasc'	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:53:49



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'hypertension'	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '10'	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:53:49



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '01 Mar 2012'	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:53:49

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 14:53:49



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:56:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:56:42
Data point term sent to Coder	System	23 Sep 2020 14:55:08
User entered 'losartan'	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'hypertension'	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '100'	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:54:48



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'un Apr 2016'	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:54:48

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 15:04:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 15:04:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 15:04:53
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 14:54:48
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:54:48



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:54:48

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 14:54:48

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 14:57:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 14:57:35
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 14:56:12
User entered 'atorvastatin'	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'hypercholesterol'	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '10'	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:55:58



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'un UNK 2014'	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:55:58



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 15:05:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 15:05:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 15:05:04
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 14:55:58
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:55:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 14:55:58

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:58:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:58:35
Data point term sent to Coder	System	23 Sep 2020 14:57:14
User entered 'singular'	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'asthma'	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '10'	(b) (4), (b) (6)	23 Sep 2020 14:56:58



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'un UNK 2019'	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:56:58



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:56:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 14:56:58

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:59:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:59:42
Data point term sent to Coder	System	23 Sep 2020 14:59:21
User entered 'metformin'	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:58:51



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered '500'	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:58:51



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 14:43:15
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2015). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'corrected start year in MH ' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	06 Nov 2020 23:52:32
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:12:30
User entered 'un UNK 2013'	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:58:51

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 14:58:51



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:45

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med WIXELA, # 30 / (Start date 01FEB2021-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:01:41
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med WIXELA, # 30 / (Start date 01FEB2021- ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'updated.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	24 Mar 2021 20:46:18
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med WIXELA, # 30 / (Start date 01FEB2021-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 16:21:54
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
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: FLUTICASONE PROPIONATE;SALMETEROL, PRODUCTSYNONYM: WIXELA INHUB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:07:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:07:16
Data point term sent to Coder	System	15 Oct 2020 15:45:41
Coding entries removed.	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:45:21

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:45

[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: FLUTICASONE PROPIONATE;SALMETEROL, PRODUCTSYNONYM: WIXELA INHUB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 09:28:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 09:28:44
Data point term sent to Coder	System	23 Sep 2020 15:00:28
User entered 'wixela'	(b) (4), (b) (6)	23 Sep 2020 14:59:43

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:59:43

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'asthma'	(b) (4), (b) (6)	23 Sep 2020 14:59:43

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User closed query 'Per CDM: If the medication for this indication is a combination drug, please consider to record the 'Dose per administration' as 500/50. And also kindly review and confirm whether the dose taken by the subject is '250/50' or '500/50'. Thankyou.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 10:19:46
Query 'Per CDM: If the medication for this indication is a combination drug, please consider to record the 'Dose per administration' as 500/50. And also kindly review and confirm whether the dose taken by the subject is '250/50' or '500/50'. Thankyou.' answered with 'data updated per query' (Site from DM).	Mario Portilla (b) (4) (b) (4)	23 Feb 2021 23:43:35
DataPoint Un-verified.	Mario Portilla (b) (4) (b) (4)	23 Feb 2021 23:43:21
User entered '250/50' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	23 Feb 2021 23:43:21
User opened query 'Per CDM: If the medication for this indication is a combination drug, please consider to record the 'Dose per administration' as 500/50. And also kindly review and confirm whether the dose taken by the subject is '250/50' or '500/50'. Thankyou.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:26:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '500-50' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 21:58:04
User entered '250-50'	(b) (4), (b) (6)	23 Sep 2020 14:59:43

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (250-50 mg) of this medication. Please review unit and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 14:43:20
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (250-50 mg) of this medication. Please review unit and update as applicable. ' answered with 'corrected to proper dose unit' (Site from DM).	Malithi Desilva (b) (4)	06 Nov 2020 23:44:54
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 23:44:19
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (250-50 mg) of this medication. Please review unit and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 14:59:43

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:59:43

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
DataPoint Un-verified.	Malithi Desilva (b) (4)	16 Apr 2021 21:09:10
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	16 Apr 2021 21:09:10
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Malithi Desilva (b) (4)	16 Apr 2021 21:09:10
New Information	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 14:59:43



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:59:43

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Malithi Desilva (b) (4)	15 Oct 2020 15:45:21
User entered 'Oral (ORAL)'	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 14:59:43

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:59:43

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'un UNK 2019'	(b) (4), (b) (6)	23 Sep 2020 14:59:43

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:59:43

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	16 Apr 2021 21:09:10
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Malithi Desilva (b) (4)	16 Apr 2021 21:09:10
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	Zoraida Cruz (b) (4)	24 Mar 2021 20:45:55
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	08 Mar 2021 23:37:51
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Mario Portilla (b) (4)	08 Mar 2021 23:37:51
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
DataPoint Un-verified.	Zoraida Cruz (b) (4)	15 Feb 2021 18:49:11
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	15 Feb 2021 18:49:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:59:43

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	16 Apr 2021 21:09:10
	(b) (4)	
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	16 Apr 2021 21:09:10
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered '01 Feb 2021' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	24 Mar 2021 20:45:55
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	08 Mar 2021 23:37:51
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4)	08 Mar 2021 23:37:51
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
DataPoint Un-verified.	Zoraida Cruz (b) (4)	15 Feb 2021 18:49:11
	(b) (4)	
User entered '01 Feb 2021' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	15 Feb 2021 18:49:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:59:43

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:59:43



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:09:10
User entered '1'	System	23 Sep 2020 14:59:43

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:09:10
User entered '1'	System	23 Sep 2020 14:59:43

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:09:10
User entered '804 (804)'	System	23 Sep 2020 14:59:43

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:03:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:03:34
Data point term sent to Coder	System	23 Sep 2020 15:02:42
User entered 'allegra'	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'seasonal allergies'	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '180'	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 15:01:41



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:01:41

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:32:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'as needed (PRN)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 16:05:03
User entered 'every other day (QOD)'	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'un UNK 2010'	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:01:41



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:05:03
User entered '1'	System	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:05:03
User entered '2'	System	23 Sep 2020 15:01:41

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:05:03
User entered '804 (804)'	System	23 Sep 2020 15:01:41

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:32:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Per MM, Please recode to ESOMEPRAZOLE for consistency' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:37:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 22:53:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	
Query 'Per MM, Please recode to ESOMEPRAZOLE for consistency' answered with 'recoded to ESOMEPRAZOLE' (Site from DM).	Malithi Desilva (b) (4)	04 Nov 2020 18:41:18
Data point term sent to Coder	System	04 Nov 2020 18:29:59
Coding entries removed.	Malithi Desilva (b) (4)	04 Nov 2020 18:29:50
User entered 'ESOMEPRAZOLE (NEXIUM)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per MM, Please recode to ESOMEPRAZOLE for consistency' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:23:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Sep 2020 15:03:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Sep 2020 15:03:34

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	23 Sep 2020 15:02:42
User entered 'nexium'	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 15:02:31



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'acid reflux'	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered '40'	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:02:31



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'un UNK 2019'	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	10 Nov 2020 23:39:42
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 15:02:31

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 15:02:31



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:05:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:05:41
Data point term sent to Coder	System	23 Sep 2020 15:04:46
User entered 'flonase'	(b) (4), (b) (6)	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'seasonal allergies'	(b) (4), (b) (6)	23 Sep 2020 15:04:36

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User closed query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of spray as there are various dosage preparation for this medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:50:14
Query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of spray as there are various dosage preparation for this medication. Please update as appropriate or provide clarification.' answered with 'formulation' (Site from DM).	Mario Portilla (b) (4)	01 Dec 2020 20:25:36
DataPoint Un-verified.	(b) (4)	01 Dec 2020 20:22:47
User entered '200' reason for change: Data Entry Error	Mario Portilla (b) (4)	01 Dec 2020 20:22:47
User opened query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of spray as there are various dosage preparation for this medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 20:01:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 15:04:36

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:32:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	01 Dec 2020 20:24:56
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	01 Dec 2020 20:23:05
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	01 Dec 2020 20:23:05
User entered 'ug (ug)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 20:23:05
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	01 Dec 2020 20:22:47
DataPoint Un-verified.	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 20:22:47
User entered 'mg (mg)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 20:22:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Other (OTHER)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:07:39
User entered 'puff (PUFF)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 18:54:34
User entered 'Other (OTHER)'	(b) (4), (b) (6)	23 Sep 2020 15:04:36

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:32:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
DataPoint Un-verified.	Mario Portilla (b) (4)	01 Dec 2020 20:24:56
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4)	01 Dec 2020 20:24:56
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "puff" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:37:06
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "puff" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'per FDA recommendations FLONASE (fluticasone propionate) is identified as a nasal spray' (Site from DM).	Malithi Desilva (b) (4)	04 Nov 2020 19:07:43
User entered 'spray' reason for change: Data Entry Error	Malithi Desilva (b) (4)	04 Nov 2020 19:07:39
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	04 Nov 2020 18:54:34
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "puff" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:57:18

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'spray'	(b) (4), (b) (6)	23 Sep 2020 15:04:36

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:32:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'as needed (PRN)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	15 Oct 2020 15:36:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 15:04:36



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'un UNK 2005'	(b) (4), (b) (6)	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 15:04:36



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:36:50
User entered '1'	System	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:36:50
User entered '1'	System	23 Sep 2020 15:04:36

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:36:50
User entered '804 (804)'	System	23 Sep 2020 15:04:36

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, PRODUCT: HYALURONATE SODIUM, PRODUCTSYNONYM: EUFLEXXA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 00:07:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 00:07:59
Data point term sent to Coder Coding entries removed.	System Zoraida Cruz (b) (4)	17 Feb 2021 22:02:43 17 Feb 2021 22:02:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, PRODUCT: HYALURONATE SODIUM, PRODUCTSYNONYM: EUFLEXXA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:55:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:55:27
Data point term sent to Coder User entered 'euflexxa (sodium hyaluronate intra-articular injection, 1%)'	System Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:27 04 Nov 2020 19:18:30

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:32:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 19:18:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 19:18:45
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	04 Nov 2020 19:18:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 19:18:30
User entered empty.	Malithi Desilva (b) (4)	04 Nov 2020 19:18:30
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
DataPoint Un-verified.	Zoraida Cruz (b) (4)	17 Feb 2021 22:02:32
	(b) (4)	
User entered 'OSTEOARTHRITIS Bilateral Knee's'	Zoraida Cruz (b) (4)	17 Feb 2021 22:02:32
reason for change: Data Entry Error	(b) (4)	
User closed query 'Per DM CLR: Please note that this	(b) (4), (b) (6)	17 Feb 2021 11:59:54
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).		
Query 'Per DM CLR: Please note that this condition	Zoraida Cruz (b) (4)	15 Feb 2021 18:53:35
is not recorded on the MH eCRF. Please review Con	(b) (4)	
Med use and add a medical condition and all		
applicable details to the appropriate MH eCRF.'		
answered with 'This condition is recorded in the		
participant's MH eCRF and Flow Sheet.' (Site from		
DM).		
User opened query 'Per DM CLR: Please note that	(b) (4), (b) (6)	27 Jan 2021 02:54:24
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).		
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'osteoarthritis in right knee'	Malithi Desilva (b) (4)	04 Nov 2020 19:18:30
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '10' reason for change: New Information	Zoraida Cruz (b) (4)	17 Feb 2021 22:02:32
	(b) (4)	
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (eg, 10 mg/ml, etc.). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:00:17
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (eg, 10 mg/ml, etc.). Please correct the dosage or provide explanation for alternate dosage.' answered with 'The participant reports 10mg/ml and was administered 2ml to the right knee only.' (Site from DM).	Zoraida Cruz (b) (4)	15 Feb 2021 18:59:49
	(b) (4)	
DataPoint Un-verified.	Zoraida Cruz (b) (4)	15 Feb 2021 18:59:43
	(b) (4)	
User entered '2' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	15 Feb 2021 18:59:43
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (eg, 10 mg/ml, etc.). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 02:54:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '10'	Malithi Desilva (b) (4)	04 Nov 2020 19:18:30
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Other (OTHER)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:32:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'mg/mL'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'other (OTHER)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:32:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'twice a year'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:32:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Other (OTHER)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Inject intra-articularly'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'UN UNK 2011'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:18:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 19:18:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 19:18:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 19:18:30

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Feb 2021 20:46:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Feb 2021 20:46:41
Data point term sent to Coder	System	15 Feb 2021 20:46:01
Coding entries removed.	Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 20:45:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:49:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:21:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:21:30
Data point term sent to Coder	System	04 Nov 2020 19:20:28
User entered 'tylenol'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:32:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:57:53
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 19:57:51
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:49:16
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:37:52
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES did not meet the AE reporting criteria. ' answered with 'Per query, information updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	08 Mar 2021 23:30:36



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES did not meet the AE reporting criteria. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Shobha Swaminathan	06 Mar 2021 11:38:59 26 Feb 2021 19:03:27
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the JOINT PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of JOINT PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:00:31
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the JOINT PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of JOINT PAIN did not meet the AE reporting criteria.' answered with 'error-corrected to reflect correct term of body aches.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 20:46:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Zoraida Cruz (b) (4)	15 Feb 2021 20:45:58
User entered 'Body aches' reason for change: Data Entry Error	(b) (4)	
	Zoraida Cruz (b) (4)	15 Feb 2021 20:45:58
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the JOINT PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of JOINT PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 02:57:35
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:49:18
User entered 'joint pain'	Malithi Desilva (b) (4)	04 Nov 2020 19:19:34
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'please review source dose administration as it states 650 mg usage twice a day. Please review, confirm and update dosage accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:40:59
Query 'please review source dose administration as it states 650 mg usage twice a day. Please review, confirm and update dosage accordingly. ' answered with 'corrected' (Site from CRA).	Malithi Desilva (b) (4) (b) (4)	06 Nov 2020 23:37:51
User entered '650' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	06 Nov 2020 23:37:44
User opened query 'please review source dose administration as it states 650 mg usage twice a day. Please review, confirm and update dosage accordingly. ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:47:51
User entered '1300'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:49:21
User entered 'mg (mg)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:49:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:49:23
User entered 'twice daily (BID)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:49:25
User entered empty.	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:49:26
User entered 'Oral (ORAL)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:49:28
User entered empty.	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:49:29
User entered '19 Oct 2020'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:49:30
User entered '0'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:49:32
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:49:33
User entered '22 Oct 2020'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:32:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:00:38
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'updated.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 22:17:21
DataPoint Un-verified.	Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 22:17:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	15 Feb 2021 22:17:14
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 02:57:50
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:49:35
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User entered '2'	System	04 Nov 2020 19:19:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User entered '1'	System	04 Nov 2020 19:19:34



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:53
User entered '804 (804)'	System	04 Nov 2020 19:19:34

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ARTHRITIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:15:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:15:40
Data point term sent to Coder	System	10 Nov 2020 21:59:45
Coding entries removed.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 21:59:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ARTHRITIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:05:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:05:52
Data point term sent to Coder	System	10 Nov 2020 19:04:53
User entered 'Tylenol Arthritis'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:32:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:04:04
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:03:55
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User closed query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 21:03:56
Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' answered with 'AE eCRF and Flow Sheet updated to match Con med.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:52:47
User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 02:59:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Headache' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 21:59:14
User entered 'covid-19 symptoms'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '650'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'mg (mg)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'three times daily (TID)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Oral (ORAL)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '2 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:24:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 22:24:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	10 Nov 2020 19:03:55
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:24:45
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 22:24:45
DataPoint Verified.	Zoraida Cruz (b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4)	10 Nov 2020 19:03:55
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:03:55



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User entered '3'	System	10 Nov 2020 19:03:55

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User entered '1'	System	10 Nov 2020 19:03:55

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:56:59
User entered '804 (804)'	System	10 Nov 2020 19:03:55

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 04:37:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 04:37:55
Data point term sent to Coder Coding entries removed.	System Zoraida Cruz (b) (4) (b) (4)	24 Mar 2021 20:50:24 24 Mar 2021 20:49:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:03:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:03:39
Data point term sent to Coder Coding entries removed.	System Mario Portilla (b) (4) (b) (4)	16 Mar 2021 20:37:27 16 Mar 2021 20:37:23
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 20:37:23

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

Name of Medication

Audit	User	Time (GMT)
User entered 'NYQUIL: Active Ingredients (In each 30 mL Dose Cup): Acetaminophen 650 mg, Dextromethorphan HBr 30 mg, Doxylamine Succinate 12.5 mg' reason for change: Data Entry Error	Mario Portilla (b) (4)	16 Mar 2021 20:37:23
User signature succeeded.	(b) (4)	
User closed query 'Per CDM: The Name of Medication includes multiple drugs for different medical conditions. Kindly consider to record each medication for respective medical condition in separate Con med loglines. Thankyou.' (Site from DM).	Shobha Swaminathan	06 Mar 2021 00:06:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	(b) (4)	05 Mar 2021 11:08:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 18:55:44
Data point term sent to Coder	(b) (4)	
Query 'Per CDM: The Name of Medication includes multiple drugs for different medical conditions. Kindly consider to record each medication for respective medical condition in separate Con med loglines. Thankyou.' answered with 'Error Corrected to NYQUIL per Line 17 Flow Sheet' (Site from DM).	Coder Import (b) (4)	03 Mar 2021 18:55:44
Coding entries removed.	System	03 Mar 2021 18:40:07
Signature has been broken.	Zoraida Cruz (b) (4)	03 Mar 2021 18:39:58
User entered 'NyQuil' reason for change: Data Entry Error	(b) (4)	
	Zoraida Cruz (b) (4)	03 Mar 2021 18:39:09
	(b) (4)	
	Zoraida Cruz (b) (4)	03 Mar 2021 18:39:09
	(b) (4)	
	Zoraida Cruz (b) (4)	03 Mar 2021 18:39:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: The Name of Medication includes multiple drugs for different medical conditions. Kindly consider to record each medication for respective medical condition in separate Con med loglines. Thankyou.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 13:25:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PHENYLEPHRIN E HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 18:23:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 18:23:06
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:03:27
Data point term sent to Coder	System	23 Feb 2021 23:47:32
DataPoint Un-verified.	Mario Portilla (b) (4) (b) (4)	23 Feb 2021 23:47:17
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	23 Feb 2021 23:47:17
User entered 'Acetaminophen 650 mg (Pain Reliever/Fever Reducer), Dextromethorphan HBr 20 mg (Cough Suppressant), Doxylamine Succinate 12.5 mg (Antihistamine), Phenylephrine HCl 10 mg (Nasal Decongestant)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	23 Feb 2021 23:47:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:21:53

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:21:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:16:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:16:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
Data point term sent to Coder	System	10 Nov 2020 21:59:46
Data point term sent to Coder	System	10 Nov 2020 19:05:55
User entered 'Nyquil (bedtime)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:05:40

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:05:40



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
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)	07 Apr 2021 14:30:36
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of Congestion. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:30:24
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, flu-like symptoms: AE #11 (cough 10/29/2020 to 12/25/2020; AE# 13 (congestion); AE # 14 (runny nose); AE# 18 (sore throat)' (Site from DM).	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 21:03:04
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 18:28:25
User signature succeeded.	Shobha Swaminathan (b) (4)	30 Mar 2021 17:12:28
Query 'Per DM CLR: Please update the indication to reflect the location and type of Congestion. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' answered with 'updated indication. ' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	24 Mar 2021 20:50:09
DataPoint Un-verified.	Zoraida Cruz (b) (4) (b) (4)	24 Mar 2021 20:49:31
Signature has been broken.	Zoraida Cruz (b) (4) (b) (4)	24 Mar 2021 20:49:31
User entered 'Nasal CONGESTION' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	24 Mar 2021 20:49:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of Congestion. Review and update indication and ensure to update Adverse event eCRF as appropriate.  ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 16:19:37
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'congestion' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 21:59:36
User entered 'covid-19 symptoms'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:05:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User closed query 'Per DM CLR-RQ: Response noted. However, please provide dose in MG instead of ML, as there are various dosage options for this drug (325/10/6.25/5, 325/15/6.25/30, 6.25/15). Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 11:54:18
Query 'Per DM CLR-RQ: Response noted. However, please provide dose in MG instead of ML, as there are various dosage options for this drug (325/10/6.25/5, 325/15/6.25/30, 6.25/15). Update the Dose and Dose Unit fields as appropriate. ' answered with 'per query, information updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 20:43:50
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 20:37:23
User entered '30' reason for change: Per Query Resolution	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 20:37:23
User opened query 'Per DM CLR-RQ: Response noted. However, please provide dose in MG instead of ML, as there are various dosage options for this drug (325/10/6.25/5, 325/15/6.25/30, 6.25/15). Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:08:06
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
User closed query 'Per CDM: As there are multiple dosage options for this drug, Kindly consider to provide the actual dose of the medication for this indication. Else clarify. Thankyou.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 11:08:20
Query 'Per CDM: As there are multiple dosage options for this drug, Kindly consider to provide the actual dose of the medication for this indication. Else clarify. Thankyou.' answered with 'Error Corrected.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	03 Mar 2021 18:40:12
Signature has been broken.	Zoraida Cruz (b) (4) (b) (4)	03 Mar 2021 18:39:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10' reason for change: Per Query Resolution	Zoraida Cruz (b) (4)	03 Mar 2021 18:39:09
User opened query 'Per CDM: As there are multiple dosage options for this drug, Kindly consider to provide the actual dose of the medication for this indication. Else clarify. Thankyou.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 13:23:07
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablespoon count as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 09:08:04
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:03:27
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablespoon count as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Per query, data updated' (Site from DM).	Mario Portilla (b) (4)	23 Feb 2021 23:47:39
DataPoint Un-verified.	Mario Portilla (b) (4)	23 Feb 2021 23:47:17
User entered '30' reason for change: Data Entry Error	Mario Portilla (b) (4)	23 Feb 2021 23:47:17
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablespoon count as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:15:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '2'	Malithi Desilva (b) (4)	10 Nov 2020 19:05:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4) Mario Portilla (b) (4)	23 Feb 2021 23:47:17
	(b) (4)	
User entered 'mL (mL)' reason for change: Data Entry Error	Mario Portilla (b) (4)	23 Feb 2021 23:47:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Other (OTHER)'	Malithi Desilva (b) (4)	10 Nov 2020 19:05:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Mario Portilla (b) (4)	23 Feb 2021 23:47:17
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4)	23 Feb 2021 23:47:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'tablespoons'	Malithi Desilva (b) (4)	10 Nov 2020 19:05:40
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'once daily (QD)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:05:40

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:05:40



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Oral (ORAL)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:05:40

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:05:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (#13). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 11:54:33
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (#13). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'please view AE #11: "cough" started 10/29/2020. this timeframe does coincide with initiation of nyquil on 11/01/2020' (Site from DM).	Mario Portilla (b) (4) (b) (4)	17 Mar 2021 15:27:38
User entered '01 Nov 2020' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	17 Mar 2021 15:26:33
DataPoint Un-verified.	Mario Portilla (b) (4) (b) (4)	17 Mar 2021 15:25:27
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	17 Mar 2021 15:25:27
User entered '04 Nov 2020' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	17 Mar 2021 15:25:27
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (#13). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:08:26
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '1 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:05:40

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:05:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:00:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:00:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	10 Nov 2020 19:05:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:00:24
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:00:24
DataPoint Verified.	Zoraida Cruz (b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4)	10 Nov 2020 19:05:40
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:05:40

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User entered '1'	System	10 Nov 2020 19:05:40



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User entered '1'	System	10 Nov 2020 19:05:40

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:06
User entered '804 (804)'	System	10 Nov 2020 19:05:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:32:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
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, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:17:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:17:39
Data point term sent to Coder	System	10 Nov 2020 19:17:12
User entered 'symbicort'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'shortness of breath'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '80/4.5' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:28:13
User entered '2'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:32:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'ug (ug)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:28:13
User entered 'puff (PUFF)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'as needed (PRN)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '7 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:10:29
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:10:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	10 Nov 2020 19:16:12
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:10:29
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 22:10:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4)	10 Nov 2020 19:16:12
	(b) (4)	



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User entered empty.	System	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User entered empty.	System	10 Nov 2020 19:16:12

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:16
User entered empty.	System	10 Nov 2020 19:16:12

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:43:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:43:58
Data point term sent to Coder	System	10 Nov 2020 20:43:25
Data point term sent to Coder	System	10 Nov 2020 19:32:06
User entered 'Zofran'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User closed query 'Per CDM: Response noted however, please verify the dates as no AE that matches this con med. Please review and update or else clarify. Thank You' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Shobha Swaminathan (b) (4)	03 Mar 2021 09:09:38 26 Feb 2021 19:03:27
Query 'Per CDM: Response noted however, please verify the dates as no AE that matches this con med. Please review and update or else clarify. Thank You' answered with 'per Query, the AE was added ' (Site from DM).	Mario Portilla (b) (4) (b) (4)	24 Feb 2021 00:07:59
User opened query 'Per CDM: Response noted however, please verify the dates as no AE that matches this con med. Please review and update or else clarify. Thank You' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:01:25
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 as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:01:25
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE eCRF and Flow Sheet updated to match Con Med indication' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:53:37
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 as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 02:59:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'nausea'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '8' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 21:58:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	10 Nov 2020 21:58:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 21:58:20
User entered '4' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 21:58:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	10 Nov 2020 21:26:36
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 21:26:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	10 Nov 2020 20:56:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 20:56:38
User entered '4' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 20:56:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	10 Nov 2020 19:32:00
User entered empty.	Malithi Desilva (b) (4)	10 Nov 2020 19:32:00



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 12 Aug 2021 13:32:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:58:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 21:58:20
User entered 'mg (mg)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 21:58:20
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:26:36
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 21:26:36
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:56:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 20:56:38
User entered 'mg (mg)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:56:38
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:32:00
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 12 Aug 2021 13:32:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:58:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 21:58:20
User entered 'twice daily (BID)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 21:58:20
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:32:00
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 12 Aug 2021 13:32:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:43:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 20:43:22
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:43:22
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:32:00
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '9 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered '0'	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:01:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:01:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	10 Nov 2020 19:32:00
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:01:46
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:01:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:39:42
User entered empty.	Malithi Desilva (b) (4)	10 Nov 2020 19:32:00
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 12 Aug 2021 13:32:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:39:42
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:43:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 20:43:27
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 20:43:27
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:32:00
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 19:32:00

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User entered '2'	System	10 Nov 2020 21:58:20
User entered empty.	System	10 Nov 2020 19:32:00

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User entered '1'	System	10 Nov 2020 21:58:20
User entered empty.	System	10 Nov 2020 19:32:00

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User entered '804 (804)'	System	10 Nov 2020 21:58:20
User entered empty.	System	10 Nov 2020 19:32:00

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON PERLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 22:03:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 22:03:54
Data point term sent to Coder	System	17 Nov 2020 22:03:17
User entered 'Tessalon perles'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User closed query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 12:02:57
Query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE eCRF and Flow Sheet updated to match Con Med indication per query' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:54:19
User opened query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:28:31
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'cough'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '200'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'mg (mg)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'once daily (QD)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Oral (ORAL)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '10 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '0'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:02:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:02:41
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	17 Nov 2020 22:02:16
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:02:41
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:02:41
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4)	17 Nov 2020 22:02:16
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User entered '1'	System	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User entered '1'	System	17 Nov 2020 22:02:16

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User entered '804 (804)'	System	17 Nov 2020 22:02:16



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 22:09:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 22:09:51
Data point term sent to Coder	System	17 Nov 2020 22:09:23
User entered 'tylenol'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
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 as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 12:04:06
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 as appropriate. ' answered with 'AE eCRF and Flow Sheet updated to match Con Med indication per query' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:55:02
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 as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 02:58:47
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'headache'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '1000'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'mg (mg)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'as needed (PRN)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Oral (ORAL)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '11 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '0'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:13:01
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:13:01
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	17 Nov 2020 22:08:30
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:13:01
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 22:13:01
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4)	17 Nov 2020 22:08:30
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User entered empty.	System	17 Nov 2020 22:08:30



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User entered empty.	System	17 Nov 2020 22:08:30

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User entered empty.	System	17 Nov 2020 22:08:30

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 12 Aug 2021 13:32:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:13:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:13:33
Data point term sent to Coder Coding entries removed.	System Malithi Desilva (b) (4)	23 Nov 2020 17:24:02 23 Nov 2020 17:23:41
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Nov 2020 21:05:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:05:06
Data point term sent to Coder Coding entries removed.	System Malithi Desilva (b) (4)	18 Nov 2020 22:26:55 18 Nov 2020 22:26:33
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Nov 2020 07:41:01

PRODUCTION RELEASE (v12.003  
EAB) (1725)

4110 of 4473

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'methylprednisolone'	Coder Import (b) (4) (b) (4) System Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 07:41:01  17 Nov 2020 22:12:26 17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'COVID19' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:23:41
User entered 'COVID19 inflammation' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:26:33
User entered 'COVID19'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '4'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'mg (mg)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'other (OTHER)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 12 Aug 2021 13:32:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '6 tabs on 10NOV, 5 tabs on 11NOV, 4 tabs 12NOV, 3 tabs 13NOV, 2 tabs 14NOV, 1 tab 15NOV'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Oral (ORAL)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '10 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '0'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '15 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User entered empty.	System	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User entered empty.	System	17 Nov 2020 22:12:21

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User entered empty.	System	17 Nov 2020 22:12:21

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:11:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:11:00
Data point term sent to Coder	System	17 Nov 2020 22:18:31
Data point term sent to Coder	System	17 Nov 2020 22:17:31
User entered 'albuterol/proair'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User closed query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 11:57:05
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:56:12
' answered with 'AE eCRF and Flow Sheet updated ' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.	(b) (4), (b) (6)	28 Jan 2021 14:29:06
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'shortness of breath'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '90'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 12 Aug 2021 13:32:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'ug (ug)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	01 Dec 2020 18:11:09
User entered 'Other (OTHER)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 12 Aug 2021 13:32:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" (micrograms) from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:46:54
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" (micrograms) from the drop down list. Please update accordingly. Else Clarify. ' answered with 'updated' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	01 Dec 2020 18:11:17
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4) (b) (4)	01 Dec 2020 18:11:09
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" (micrograms) from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 12:42:55
User entered 'mcg'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'three times daily (TID)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 12 Aug 2021 13:32:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 22:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 22:17:48
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 22:17:14
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '10 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '0'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:18:49
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '17 Nov 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4)	18 Nov 2020 22:18:49
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User entered '3'	System	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User entered '1'	System	17 Nov 2020 22:17:14

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:16
User entered '804 (804)'	System	17 Nov 2020 22:17:14

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:37:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:37:50
Data point term sent to Coder	System	18 Nov 2020 22:22:51
Data point term sent to Coder	System	18 Nov 2020 22:21:47
User entered 'Advil'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User closed query 'Per CDM: Response noted however, please verify the dates as no AE that matches this con med. Please review and update or else clarify. Thank You' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Shobha Swaminathan	03 Mar 2021 09:10:05
Query 'Per CDM: Response noted however, please verify the dates as no AE that matches this con med. Please review and update or else clarify. Thank You' answered with 'Per query, data updated' (Site from DM).	(b) (4) Mario Portilla (b) (4) (b) (4)	26 Feb 2021 19:03:27
24 Feb 2021 00:23:31		
User opened query 'Per CDM: Response noted however, please verify the dates as no AE that matches this con med. Please review and update or else clarify. Thank You' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:07:33
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 as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:07:33
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 as appropriate. ' answered with 'AE eCRF and Flow Sheet updated.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:56:33
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 as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 02:53:49
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 22:22:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 22:22:04

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
User entered 'headache' reason for change: Data Entry Error	Malithi Desilva (b) (4)	18 Nov 2020 22:22:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Nov 2020 22:21:35
	Malithi Desilva (b) (4)	18 Nov 2020 22:21:35
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '400'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'mg (mg)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'once daily (QD)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Oral (ORAL)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 12 Aug 2021 13:32:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 12 Aug 2021 13:32:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '03 Nov 2020' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	01 Dec 2020 21:33:16
User entered '17 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '0'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:14:39
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Zoraida Cruz (b) (4)	17 Feb 2021 22:14:39
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	18 Nov 2020 22:21:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '16 Dec 2020' reason for change: Data Entry Error	(b) (4) Mario Portilla (b) (4)	24 Feb 2021 00:23:00
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4) System	17 Feb 2021 23:56:54
User entered '15 Dec 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 23:56:54
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	17 Feb 2021 22:14:39
DataPoint Un-verified.	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 22:14:39
User entered '15 Dec 2021' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 22:14:39
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 22:21:35

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User entered '1'	System	18 Nov 2020 22:21:35



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User entered '1'	System	18 Nov 2020 22:21:35

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:24
User entered '804 (804)'	System	18 Nov 2020 22:21:35

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 16:55:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 16:55:57
Data point term sent to Coder	System	03 Dec 2020 16:55:29
User entered 'PEPCID (famotidine)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:54:50
Data point term sent to Coder	System	03 Dec 2020 16:46:22
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:46:01
User entered 'PEPCID (omeprazole)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:46:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:13
Data point term sent to Coder	System	23 Nov 2020 17:09:27
User entered 'pepcid'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'heartburn'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '20'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'mg (mg)'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'as needed (PRN)'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 12 Aug 2021 13:32:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Oral (ORAL)'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '14 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '0'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:09:06

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:09:06

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
Query 'Per DM CLR: Please note this AE# overlaps with AE#21 COUGH 16Feb2021-ongoing. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:12:10
User opened query 'Per DM CLR: Please note this AE# overlaps with AE#21 COUGH 16Feb2021-ongoing. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:11:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Dec 2020 23:07:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 23:07:44
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
Data point term sent to Coder	System	03 Dec 2020 16:18:49
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:18:19
User entered 'OMEPRAZOLE (Prilosec)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:18:19

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Dec 2020 16:11:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Dec 2020 16:11:01
Data point term sent to Coder	System	03 Dec 2020 16:10:35
User entered 'Omeprazole' reason for change: Data Entry Error	Mario Portilla (b) (4)	03 Dec 2020 16:09:48
	(b) (4)	
Data point term sent to Coder	System	03 Dec 2020 16:05:30
User entered 'Prevacid (lansoprazole)'	Mario Portilla (b) (4)	03 Dec 2020 16:05:02
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Heart Burn'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 12 Aug 2021 13:32:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 16:09:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 16:09:48
User entered '20' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:09:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 16:05:02
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 12 Aug 2021 13:32:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 16:09:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 16:09:48
User entered 'mg (mg)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:09:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 16:05:02
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 12 Aug 2021 13:32:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'once daily (QD)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:09:48
User entered 'as needed (PRN)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Oral (ORAL)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 12 Aug 2021 13:32:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'un Nov 2020' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 17:05:06
User entered '28 Nov 2020'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:06:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:06:17
DataPoint Verified.	Zoraida Cruz (b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 16:09:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 16:09:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Mario Portilla (b) (4)	03 Dec 2020 16:09:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 16:05:02
User entered empty.	Mario Portilla (b) (4)	03 Dec 2020 16:05:02
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:06:17
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:06:17
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Mario Portilla (b) (4)	03 Dec 2020 16:05:02
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 12 Aug 2021 13:32:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:05:02

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User entered 'I'	System	03 Dec 2020 16:09:48
User entered empty.	System	03 Dec 2020 16:05:02

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User entered '1'	System	03 Dec 2020 16:09:48
User entered empty.	System	03 Dec 2020 16:05:02

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:48
User entered '804 (804)'	System	03 Dec 2020 16:09:48
User entered empty.	System	03 Dec 2020 16:05:02

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User coded data point as ATC: ALIMINARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: LANSOPRAZOLE, PRODUCTSYNONYM: PREVACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Dec 2020 00:56:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:56:45
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
Data point term sent to Coder	System	03 Dec 2020 16:58:31
User entered 'Prevacid (Lansoprazole)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Heart Burn'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '30'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'mg (mg)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'as needed (PRN)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 12 Aug 2021 13:32:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Oral (ORAL)'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 12 Aug 2021 13:32:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Dec 2020 16:59:39
User entered 'un Nov 2020' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:59:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Dec 2020 16:58:13
User entered 'Nov 2020' (non-conformant).	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered '0'	Mario Portilla (b) (4) (b) (4)	03 Dec 2020 16:58:13

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:05:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:05:44
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Yes (Y)'	Mario Portilla (b) (4)	03 Dec 2020 16:58:13
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
DataPoint Un-verified.	(b) (4)	
	Zoraida Cruz (b) (4)	13 Jan 2021 22:05:44
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 22:05:44
DataPoint Verified.	Zoraida Cruz (b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered empty.	Mario Portilla (b) (4)	03 Dec 2020 16:58:13
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 12 Aug 2021 13:32:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 12:09:30
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'Updated the answer to NO not taken for solicited event. ' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 22:18:47
DataPoint Un-verified.	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 22:17:10
User entered 'No (N)' reason for change: New Information	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 22:17:10

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 12 Aug 2021 13:32:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:29:59
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Mario Portilla (b) (4)	03 Dec 2020 16:59:39
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	03 Dec 2020 16:59:17
User entered 'Yes (Y)'	Mario Portilla (b) (4)	03 Dec 2020 16:58:13

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User entered empty.	System	03 Dec 2020 16:58:13



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User entered empty.	System	03 Dec 2020 16:58:13

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:57
User entered empty.	System	03 Dec 2020 16:58:13

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 06:52:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 06:52:45
Data point term sent to Coder	System	17 Feb 2021 22:29:26
User entered 'Advil'	Zoraida Cruz (b) (4) (b) (4)	17 Feb 2021 22:28:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'body aches, muscle aches'	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '600'	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'mg (mg)'	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

US3842040

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'as needed (PRN)'	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 12 Aug 2021 13:32:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'Oral (ORAL)'	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 12 Aug 2021 13:32:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '17 Feb 2021'	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	17 Feb 2021 22:28:34
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 22:28:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 22:28:34

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 22:28:34

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ARTHRITIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Feb 2021 23:43:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 23:43:12
Data point term sent to Coder	System	23 Feb 2021 23:42:28
User entered 'Tylenol Arthritis'	Mario Portilla (b) (4) (b) (4)	23 Feb 2021 23:41:27

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'No (N)'	(b) (4)	23 Feb 2021 23:41:27
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Sore throat, headache, chills, body aches'	(b) (4) Mario Portilla (b) (4) (b) (4)	23 Feb 2021 23:41:27

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '1300'	(b) (4)	23 Feb 2021 23:41:27
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'mg (mg)'	Mario Portilla (b) (4)	23 Feb 2021 23:41:27
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 12 Aug 2021 13:32:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	23 Feb 2021 23:41:27
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'three times daily (TID)'	(b) (4)	23 Feb 2021 23:41:27
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	23 Feb 2021 23:41:27
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered 'Oral (ORAL)'	(b) (4)	23 Feb 2021 23:41:27
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered empty.	(b) (4)	23 Feb 2021 23:41:27
	Mario Portilla (b) (4)	
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 12 Aug 2021 13:32:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User closed query 'Per DM CLR:Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:37:22
Query 'Per DM CLR:Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' answered with 'AE #23 and AE #2date 2/15/2021 which is prior to this conmed' (Site from DM).	Mario Portilla (b) (4) (b) (4)	23 Mar 2021 16:01:39
User opened query 'Per DM CLR:Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:09:41
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:03:27
User entered '21 Feb 2021'	Mario Portilla (b) (4) (b) (4)	23 Feb 2021 23:41:27

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
User entered '0'	(b) (4)	23 Feb 2021 23:41:27
	Mario Portilla (b) (4)	
	(b) (4)	



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
Signature has been broken.	(b) (4)	23 Mar 2021 16:03:43
	Mario Portilla (b) (4)	
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	23 Mar 2021 16:03:43
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	23 Feb 2021 23:41:27
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
Signature has been broken.	(b) (4)	23 Mar 2021 16:03:43
	Mario Portilla (b) (4)	
	(b) (4)	
User entered '08 Mar 2021' reason for change: Data Entry Error	Mario Portilla (b) (4)	23 Mar 2021 16:03:43
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	23 Feb 2021 23:41:27
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 12 Aug 2021 13:32:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User closed query 'Per DM CLR: Was this medication taken for solicited event= YES. However, note that Solicited ARs are collected on Blinded Phase only per protocol. Review if this is considered as UNSOLICITED event per protocol (MAAEs-including any signs and symptoms of Covid-19, SAEs, AEs leading to withdrawal). If yes, please update this field to "No".' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 May 2021 15:18:11
	Shobha Swaminathan	28 Apr 2021 10:35:18
	(b) (4)	
Query 'Per DM CLR: Was this medication taken for solicited event= YES. However, note that Solicited ARs are collected on Blinded Phase only per protocol. Review if this is considered as UNSOLICITED event per protocol (MAAEs-including any signs and symptoms of Covid-19, SAEs, AEs leading to withdrawal). If yes, please update this field to "No".' answered with 'per eCRFV5 pg48: **Any solicited AR that meets any of the following criteria must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF: Solicited local or systemic AR lasting beyond 7 days post-injection Participant received injection 15FEB2021, symptoms started on day 7 and continued till 08MAR2021. Please advise if this does not apply. Participant also has history of covid19 infection, so SARs were expected to be seen' (Site from DM).	Malithi Desilva (b) (4)	07 Apr 2021 20:57:38
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	07 Apr 2021 20:56:38
Signature has been broken.	(b) (4)	
	Mario Portilla (b) (4)	07 Apr 2021 20:47:59
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	07 Apr 2021 20:47:59
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 12 Aug 2021 13:32:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event= YES. However, note that Solicited ARs are collected on Blinded Phase only per protocol. Review if this is considered as UNSOLICITED event per protocol (MAAEs-including any signs and symptoms of Covid-19, SAEs, AEs leading to withdrawal). If yes, please update this field to "No".' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	07 Apr 2021 14:36:03
	Shobha Swaminathan	26 Feb 2021 19:03:27
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	23 Feb 2021 23:41:27
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User entered '3'	System	23 Feb 2021 23:41:27

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User entered '1'	System	23 Feb 2021 23:41:27

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:58
User entered '804 (804)'	System	23 Feb 2021 23:41:27

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 12 Aug 2021 13:32:45

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 12:39:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 12:39:56
User signature succeeded.	Shobha Swaminathan (b) (4)	06 Mar 2021 00:06:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 07:53:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 07:53:05
Data point term sent to Coder	System	03 Mar 2021 14:25:29
User entered 'Botox'	Zoraida Cruz (b) (4) (b) (4)	03 Mar 2021 14:25:01



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'Cosmetic'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered '5'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'IU (IU)'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

US3842040

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'other (OTHER)'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 12 Aug 2021 13:32:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'every 3 to 4 months'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'Other (OTHER)'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'Intradermally'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'un Dec 2020'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:06:55
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	03 Mar 2021 14:25:01
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:25:01

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:25:01



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:25:01

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 12 Aug 2021 13:32:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 05:12:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 05:12:25
Data point term sent to Coder	System	19 Mar 2021 15:23:14
User entered 'NYQUIL: ACTIVE INGREDIENTS (IN EACH 30 ML DOSE CUP): ACETAMINOPHEN 650 MG, DEXTROMETHORPHAN HBR 30 MG, DOXYLAMINE SUCCINATE 12.5 MG'	Mario Portilla (b) (4) (b) (4)	19 Mar 2021 15:22:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'No (N)'	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 12 Aug 2021 13:32:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
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 10:00:49
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 'Please see flu-like symptoms: AE 13, 14, 18, 20, 22 ; this medication is indicated for these symptoms tht started 10/29/20 and persevered thru november and december 2020' (Site from DM).	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 21:08:13
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 18:30:29
User signature succeeded.	Shobha Swaminathan (b) (4)	30 Mar 2021 17:12:28
User entered 'runny nose'	Mario Portilla (b) (4) (b) (4)	19 Mar 2021 15:22:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered '30'	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'mL (mL)'	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered empty.	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'once daily (QD)'	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered empty.	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'Oral (ORAL)'	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered empty.	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered '01 Nov 2020'	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered '0'	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'No (N)'	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered '20 Nov 2020'	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'No (N)'	(b) (4)	19 Mar 2021 15:22:47
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User entered '1'	System	19 Mar 2021 15:22:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User entered '1'	System	19 Mar 2021 15:22:47

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:10
User entered '804 (804)'	System	19 Mar 2021 15:22:47

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 12 Aug 2021 13:32:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
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: TIOTROPIUM BROMIDE, PRODUCTSYNONYM: SPIRIVA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 14:02:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 14:02:37
Data point term sent to Coder	System	22 Mar 2021 19:46:52
User entered 'Spiriva HandiHaler (tiotropium bromide)'	Mario Portilla (b) (4) (b) (4) (b) (4)	22 Mar 2021 19:45:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'Asthma'	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered '2.5'	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'ug (ug)'	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	



US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 12 Aug 2021 13:32:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'twice daily (BID)'	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 12 Aug 2021 13:32:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 12 Aug 2021 13:32:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered '20 Mar 2021'	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	22 Mar 2021 19:45:58
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Mar 2021 19:45:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 19:45:58

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 19:45:58

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 12 Aug 2021 13:32:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
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.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 11:38:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 11:38:26
Data point term sent to Coder	System	22 Mar 2021 19:52:03
User entered 'Aspirin'	Mario Portilla (b) (4) (b) (4)	22 Mar 2021 19:51:17

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'No (N)'	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'anticoagulant (COVID)'	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered '81'	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
	(b) (4)	
User entered 'mg (mg)'	Mario Portilla (b) (4)	22 Mar 2021 19:51:17
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered empty.	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'once daily (QD)'	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered empty.	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'Oral (ORAL)'	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered empty.	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered '01 Nov 2020'	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered '0'	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 12 Aug 2021 13:32:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
Signature has been broken.	(b) (4)	16 Apr 2021 21:13:51
User entered 'No (N)' reason for change: New Information	Malithi Desilva (b) (4)	16 Apr 2021 21:13:51
User signature succeeded.	(b) (4)	30 Mar 2021 17:12:28
User entered 'Yes (Y)'	Mario Portilla (b) (4)	22 Mar 2021 19:51:17
	(b) (4)	

US3842040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 12 Aug 2021 13:32:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
Signature has been broken.	(b) (4)	16 Apr 2021 21:13:51
User entered '22 Mar 2021' reason for change: New Information	Malithi Desilva (b) (4)	16 Apr 2021 21:13:51
User signature succeeded.	(b) (4)	30 Mar 2021 17:12:28
User entered empty.	Mario Portilla (b) (4)	22 Mar 2021 19:51:17
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:12:28
User entered 'No (N)'	(b) (4)	22 Mar 2021 19:51:17
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User entered '1'	System	22 Mar 2021 19:51:17

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User entered '1'	System	22 Mar 2021 19:51:17

**US3842040**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 12 Aug 2021 13:32:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:19
User entered '804 (804)'	System	22 Mar 2021 19:51:17

**US3842040**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 12 Aug 2021 13:32:45**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered 'No (N)'	Malithi Desilva (b) (4)	10 Nov 2020 19:25:10
	(b) (4)	



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered	(b) (4), (b) (6)	05 Nov 2020 16:21:43
'USA-US110-2020-MRNA-1273-P301000001'	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Shobha'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Swaminathan'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:32:45

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:15:14
Un-reviewed for Safety.	System	01 Dec 2020 15:25:15
DataPoint Un-verified.	System	01 Dec 2020 15:25:15
User entered '185, south orange ave'	System	01 Dec 2020 15:25:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Un-reviewed for Safety.	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
User entered '225 Warren Street' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '185, south orange ave'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Newark'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:59:22

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '07103'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered 'US'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	01 Apr 2021 20:23:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '6'	System	26 Jan 2021 01:44:55
User entered '5'	System	05 Jan 2021 20:15:01
User entered '4'	System	11 Dec 2020 14:01:38
User entered '3'	System	02 Dec 2020 13:15:22
User entered '2'	System	01 Dec 2020 15:25:15
User entered '1'	System	05 Nov 2020 16:29:35



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'USA-US110-2020-MRNA-1273-P301000001'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Shobha'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Swaminathan'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:32:45

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:15:14
Un-reviewed for Safety.	System	01 Dec 2020 15:25:15
DataPoint Un-verified.	System	01 Dec 2020 15:25:15
User entered '185, south orange ave'	System	01 Dec 2020 15:25:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Un-reviewed for Safety.	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
User entered '225 Warren Street' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '185, south orange ave'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Newark'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:59:22

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '07103'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered 'US'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	01 Apr 2021 20:23:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '6'	System	26 Jan 2021 01:44:55
User entered '5'	System	05 Jan 2021 20:15:01
User entered '4'	System	11 Dec 2020 14:01:38
User entered '3'	System	02 Dec 2020 13:15:22
User entered '2'	System	01 Dec 2020 15:25:15
User entered '1'	System	05 Nov 2020 16:29:35



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered '05/Nov/2020 16:29'	System	05 Nov 2020 16:29:35

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:32:45

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:29:35
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 16:29:25

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'USA-US110-2020-MRNA-1273-P301000001'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Shobha'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Swaminathan'	System	05 Nov 2020 16:21:43

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:32:45

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:15:14
Un-reviewed for Safety.	System	01 Dec 2020 15:25:15
DataPoint Un-verified.	System	01 Dec 2020 15:25:15
User entered '185, south orange ave'	System	01 Dec 2020 15:25:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Un-reviewed for Safety.	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
User entered '225 Warren Street' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '185, south orange ave'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Newark'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:59:22

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '07103'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered 'US'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	01 Apr 2021 20:23:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '6'	System	26 Jan 2021 01:44:55
User entered '5'	System	05 Jan 2021 20:15:01
User entered '4'	System	11 Dec 2020 14:01:38
User entered '3'	System	02 Dec 2020 13:15:22
User entered '2'	System	01 Dec 2020 15:25:15
User entered '1'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '01/Dec/2020 15:25'	(b) (4) System	01 Dec 2020 15:25:15

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:32:45

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:15:14
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 15:25:15

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'USA-US110-2020-MRNA-1273-P301000001'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Shobha'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Swaminathan'	System	05 Nov 2020 16:21:43

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:32:45

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:15:14
Un-reviewed for Safety.	System	01 Dec 2020 15:25:15
DataPoint Un-verified.	System	01 Dec 2020 15:25:15
User entered '185, south orange ave'	System	01 Dec 2020 15:25:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Un-reviewed for Safety.	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
User entered '225 Warren Street' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '185, south orange ave'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Newark'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:59:22

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '07103'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered 'US'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	01 Apr 2021 20:23:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '6'	System	26 Jan 2021 01:44:55
User entered '5'	System	05 Jan 2021 20:15:01
User entered '4'	System	11 Dec 2020 14:01:38
User entered '3'	System	02 Dec 2020 13:15:22
User entered '2'	System	01 Dec 2020 15:25:15
User entered '1'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '02/Dec/2020 08:15'	(b) (4) System	02 Dec 2020 13:15:22

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:32:45

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 14:01:22
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 13:15:22

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'USA-US110-2020-MRNA-1273-P301000001'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Shobha'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Swaminathan'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	



US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:32:45

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:15:14
Un-reviewed for Safety.	System	01 Dec 2020 15:25:15
DataPoint Un-verified.	System	01 Dec 2020 15:25:15
User entered '185, south orange ave'	System	01 Dec 2020 15:25:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Un-reviewed for Safety.	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
User entered '225 Warren Street' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '185, south orange ave'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Newark'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered empty.	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
	(b) (4)	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '07103'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered 'US'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	01 Apr 2021 20:23:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '6'	System	26 Jan 2021 01:44:55
User entered '5'	System	05 Jan 2021 20:15:01
User entered '4'	System	11 Dec 2020 14:01:38
User entered '3'	System	02 Dec 2020 13:15:22
User entered '2'	System	01 Dec 2020 15:25:15
User entered '1'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '11/Dec/2020 09:01'	(b) (4) System	11 Dec 2020 14:01:38

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:32:45

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:14:47
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 14:01:38



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'USA-US110-2020-MRNA-1273-P301000001'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Shobha'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Swaminathan'	System	05 Nov 2020 16:21:43

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:32:45

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:15:14
Un-reviewed for Safety.	System	01 Dec 2020 15:25:15
DataPoint Un-verified.	System	01 Dec 2020 15:25:15
User entered '185, south orange ave'	System	01 Dec 2020 15:25:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Un-reviewed for Safety.	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
User entered '225 Warren Street' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '185, south orange ave'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Newark'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:59:22

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '07103'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered 'US'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	01 Apr 2021 20:23:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '6'	System	26 Jan 2021 01:44:55
User entered '5'	System	05 Jan 2021 20:15:01
User entered '4'	System	11 Dec 2020 14:01:38
User entered '3'	System	02 Dec 2020 13:15:22
User entered '2'	System	01 Dec 2020 15:25:15
User entered '1'	System	05 Nov 2020 16:29:35



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '05/Jan/2021 20:14'	(b) (4) System	05 Jan 2021 20:15:01

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 12 Aug 2021 13:32:45

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 01:44:43
User entered 'I'	(b) (4), (b) (6)	05 Jan 2021 20:15:01

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'USA-US110-2020-MRNA-1273-P301000001'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Shobha'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Swaminathan'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:32:45

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:15:14
Un-reviewed for Safety.	System	01 Dec 2020 15:25:15
DataPoint Un-verified.	System	01 Dec 2020 15:25:15
User entered '185, south orange ave'	System	01 Dec 2020 15:25:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Un-reviewed for Safety.	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
User entered '225 Warren Street' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '185, south orange ave'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Newark'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered empty.	Malithi Desilva (b) (4) (b) (4)	10 Nov 2020 16:59:22

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '07103'	System	05 Nov 2020 16:21:43



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered 'US'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	01 Apr 2021 20:23:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '6'	System	26 Jan 2021 01:44:55
User entered '5'	System	05 Jan 2021 20:15:01
User entered '4'	System	11 Dec 2020 14:01:38
User entered '3'	System	02 Dec 2020 13:15:22
User entered '2'	System	01 Dec 2020 15:25:15
User entered '1'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered '25/Jan/2021 20:44'	(b) (4) System	26 Jan 2021 01:44:55

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 12 Aug 2021 13:32:45

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 20:22:50
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 01:44:55

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'USA-US110-2020-MRNA-1273-P301000001'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Shobha'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Swaminathan'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:32:45

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:59
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:15:14
Un-reviewed for Safety.	System	01 Dec 2020 15:25:15
DataPoint Un-verified.	System	01 Dec 2020 15:25:15
User entered '185, south orange ave'	System	01 Dec 2020 15:25:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
Un-reviewed for Safety.	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
User entered '225 Warren Street' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '185, south orange ave'	System	05 Nov 2020 16:21:43

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered 'Newark'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	



**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered empty.	Malithi Desilva (b) (4)	10 Nov 2020 16:59:22
	(b) (4)	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:29:18
User entered '07103'	(b) (4), (b) (6)	05 Nov 2020 16:21:43
	System	

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:09:12
User entered 'US'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:32:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	01 Apr 2021 20:23:06
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:47:46
	(b) (4)	
User entered '6'	System	26 Jan 2021 01:44:55
User entered '5'	System	05 Jan 2021 20:15:01
User entered '4'	System	11 Dec 2020 14:01:38
User entered '3'	System	02 Dec 2020 13:15:22
User entered '2'	System	01 Dec 2020 15:25:15
User entered '1'	System	05 Nov 2020 16:29:35

**US3842040**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (7)**

**Generated On: 12 Aug 2021 13:32:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered '01/Apr/2021 16:23'	(b) (4) System	01 Apr 2021 20:23:06

US3842040

Folder: SAE USA-US110-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 12 Aug 2021 13:32:45

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:06
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:35:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:23:06