

US3752162 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:26:31

All time stamps listed in this document are displayed in GMT

US3752162

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 18:37:01

Generated On: 12 Aug 2021 13:26:31

[Participant ID](#)

US3752162

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

US3752162

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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

Visit date (dd MMM yyyy)	19 AUG 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	SCRN
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US3752162

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 18:37:04

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Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input 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) 12 Feb 2021 18:37:04

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 18:37:04

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 18:37:04

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Condition	VISION DISTURBANCE: (UNKNOWN DIAGNOSIS)
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	HYPERTRIGLYCERIDEMIA
Start date (dd MMM yyyy)	UN UNK 1976
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 1976
Start Year (derived)	1976
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	CHOLECYSTECTOMY (ASSOCIATED CONDITION UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	GERD/REFLUX
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	SKIN CANCER REMOVAL RIGHT HAND (UNKNOWN IF BENIGN OR MALIGNANT)
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	LOW BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	VERTIGO
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 (9)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	COLONOSCOPY (UNDERLYING CONDITION UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	WEARS GLASSES (UNKNOWN DIAGNOSIS)
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	BILATERAL CATARACT SURGERY
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	ATTENTION DEFICIT DISORDER WITHOUT HYPERACTIVITY
Start date (dd MMM yyyy)	13 OCT 2017
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)	OCT 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	GILBERT'S SYNDROME
Start date (dd MMM yyyy)	16 MAY 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Condition	PAROXYSMAL ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	16 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:40 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:40
Height (<i>xxx.x</i>)	68.0 in
Weight (<i>xxx.x</i>)	209.0 lb
BMI (<i>xxx.x</i>)	31.84479 kg/m ²
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) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:37:04

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:37:04

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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

Visit date (dd MMM yyyy)	19 AUG 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	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 187139

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☒ No ☐

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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)	19 AUG 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:40
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	062 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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)	19 AUG 2020
Time of assessment (00:00-23:59)	16:10 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 16:10
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 15:34 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 15:34

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) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 AUG 2020

Collection time (00:00-23:59)

14:50 (24 HR)

Collection date and time (derived)

19 AUG 2020 14:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:47	19 AUG 2020 14:47
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

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 13:26:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 15:58

PC Open Date & Time

19 AUG 2020 15:54

PC Close Date & Time

19 AUG 2020 18:24

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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 98.8 °F

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

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

PC Time Stamp	19 AUG 2020 19:22
PC Open Date & Time	19 AUG 2020 19:19
PC Close Date & Time	20 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

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 ☒

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 20 AUG 2020 19:37

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 17:41

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 22:39

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

24 AUG 2020 08:32

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

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

97.4 °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

25 AUG 2020 09:35

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

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

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 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 16:03

PC Open Date & Time

19 AUG 2020 15:54

PC Close Date & Time

19 AUG 2020 18:24

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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

19 AUG 2020 19:22

PC Open Date & Time

19 AUG 2020 19:19

PC Close Date & Time

20 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

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

20 AUG 2020 19:40

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

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

21 AUG 2020 17:41

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

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

22 AUG 2020 22:40

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

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

24 AUG 2020 08:32

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

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

25 AUG 2020 09:36

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE. Please select one response below	None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/> No <input type="radio"/>
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 <input type="radio"/> No <input type="radio"/>
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 <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 16:05
PC Open Date & Time	19 AUG 2020 15:54
PC Close Date & Time	19 AUG 2020 18:24

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 19:23
PC Open Date & Time	19 AUG 2020 19:19
PC Close Date & Time	20 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

		Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 19:39	
PC Open Date & Time	20 AUG 2020 12:00	
PC Close Date & Time	21 AUG 2020 11:59	

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 17:42
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

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 ☒

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 22:40
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

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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US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 08:33
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

		Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 09:36	
PC Open Date & Time	24 AUG 2020 12:00	
PC Close Date & Time	25 AUG 2020 11:59	

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

Yes ☐

PC Time stamp

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3752162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:37:05

Generated On: 12 Aug 2021 13:26:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:37:05

Generated On: 12 Aug 2021 13:26:31

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 SEP 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:36
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:37:05

Generated On: 12 Aug 2021 13:26:31

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)	16 SEP 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:25
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3752162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:37:05

Generated On: 12 Aug 2021 13:26:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:37:05

Generated On: 12 Aug 2021 13:26:31

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 SEP 2020

What was the treatment time? (00:00-23:59) 11:06 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 11:06

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

US3752162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:37:05

Generated On: 12 Aug 2021 13:26:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

10:36 (24 HR)

Collection date and time (derived)

16 SEP 2020 10:36

US3752162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:37:05

Generated On: 12 Aug 2021 13:26:31

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:34	16 SEP 2020 10:34
Nasopharyngeal Swab 2	No		

US3752162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:37:05

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 11:40

PC Open Date & Time

16 SEP 2020 11:26

PC Close Date & Time

16 SEP 2020 13:56

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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 98.1 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 17 SEP 2020 09:54

PC Open Date & Time 16 SEP 2020 14:51

PC Close Date & Time 17 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

18 SEP 2020 09:40

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

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

20 SEP 2020 09:50

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

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

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

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 15:58

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

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

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

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 11:40

PC Open Date & Time

16 SEP 2020 11:26

PC Close Date & Time

16 SEP 2020 13:56

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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

17 SEP 2020 09:54

PC Open Date & Time

16 SEP 2020 14:51

PC Close Date & Time

17 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

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

18 SEP 2020 09:41

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

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

20 SEP 2020 08:53

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

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 SEP 2020 15:59

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 11:41
PC Open Date & Time	16 SEP 2020 11:26
PC Close Date & Time	16 SEP 2020 13:56

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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

No ☐

Yes ☒

PC Time stamp	17 SEP 2020 09:56
PC Open Date & Time	16 SEP 2020 14:51
PC Close Date & Time	17 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

	Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 09:40
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

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)

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 08:53
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

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)

112 of 3287

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

Yes ☐

PC Time stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

		Yes <input type="checkbox"/>
PC Time stamp	21 SEP 2020 15:59	
PC Open Date & Time	21 SEP 2020 12:00	
PC Close Date & Time	22 SEP 2020 11:59	

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

116 of 3287

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

Yes ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 16:18:31

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:28:49

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 DEC 2020 11:30:18
Patient Cloud Open Date & Time	04 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
138 of 3287	

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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	22 DEC 2020 08:35:25
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

29 DEC 2020 12:01:36

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 17:44:40

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 FEB 2021 18:01:06
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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	15 FEB 2021 18:37:34
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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 MAR 2021 17:32:26
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

16 MAR 2021 12:55:24

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

21 MAR 2021 12:01:00

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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	30 MAR 2021 21:26:51
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 APR 2021 18:39:03
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 12:01:13

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 APR 2021 13:05:12

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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°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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Patient Cloud Open Date & Time	10 DEC 2021 00:01
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Patient Cloud Close Date & Time	14 DEC 2021 23:59
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US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

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19 JUL 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 JUL 2022 00:01

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26 JUL 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

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09 AUG 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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16 AUG 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

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23 AUG 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

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30 AUG 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

13 SEP 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

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20 SEP 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

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27 SEP 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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 <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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3752162

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:26:31

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		09 MAR 2021 17:32:47

US3752162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:28:49

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:28:49

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:28:49

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:28:49

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

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

Visit date (dd MMM yyyy)	24 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	VISIT4
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US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:16:34

Generated On: 12 Aug 2021 13:26:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 MAR 2021
Time of assessment (00:00-23:59)	11:07 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 11:07
Temperature (xxx.x)	98.0 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752162

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3752162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

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

Collection date (dd MMM yyyy)	24 MAR 2021
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Collection time (00:00-23:59)	11:15 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	24 MAR 2021 11:15
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US3752162

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 01:15:46

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 01:15:46

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 18:37:02

Generated On: 12 Aug 2021 13:26:31

Date of Contact	19 OCT 2020
Time of Contact	16:00
Date and Time of Contact (derived)	19 OCT 2020 16:00
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>

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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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EAB) (1725)

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US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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 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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US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 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"/>

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	88 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 checked="" type="radio"/>
	Mild	<input 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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EAB) (1725)

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 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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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 (3)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 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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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 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 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.6 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 checked="" 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 (4)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 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 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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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 (5)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	99.9 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 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 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 (5)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 (6)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 (6)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.0 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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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 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 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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 (7)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	100.0 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 type="radio"/>
	Moderate	<input checked="" 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 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 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 (7)

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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 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 (8)

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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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Form: Symptom Log (8)

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	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.0 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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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 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 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 (8)

Data signed: (b) (4) 23 Apr 2021 14:51:13

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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 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 type="radio"/>
	Mild	<input checked="" 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 (9)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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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Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.1 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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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 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 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 (9)

Data signed: (b) (4) 23 Apr 2021 14:51:13

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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 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) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.6 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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	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 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 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 (10)

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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 (11)

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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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Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.2 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 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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	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 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 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 (11)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 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 19 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.6 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 (12)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 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 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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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 19 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 (13)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 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 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 (13)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 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 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 (13)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 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 (14)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 (14)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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 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 (14)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 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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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 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 19 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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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Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 (15)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 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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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 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 (16)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 checked="" type="radio"/>
	Mild	<input 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) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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 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"/>

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 ☐

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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"/>

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	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	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 checked="" type="radio"/>
	Mild	<input 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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EAB) (1725)

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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 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"/>

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:51:13

Generated On: 12 Aug 2021 13:26:31

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 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"/>

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 18:37:02

Generated On: 12 Aug 2021 13:26:31

Date of Visit 27 OCT 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 27 OCT 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

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 18 OCT 2020

End Date 18 OCT 2020

Oxygen Saturation 88 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

If Yes to either Did subject require any of the following:

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

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EAB) (1725)

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US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Mar 2021 16:18:31

Generated On: 12 Aug 2021 13:26:31

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 17 Mar 2021 20:26:27

Generated On: 12 Aug 2021 13:26:31

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	Yes	27 OCT 2020
Day 14	Yes	30 OCT 2020
Day 21	Yes	6 NOV 2020
Day 28	Yes	18 NOV 2020

US3752162

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 14:04:49

Generated On: 12 Aug 2021 13:26:31

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 SICKD1

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 14:04:49

Generated On: 12 Aug 2021 13:26:31

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) _____

US3752162

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

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.

US3752162

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 14:04:49

Generated On: 12 Aug 2021 13:26:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	11:19 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 11:19
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 13:07:46

Generated On: 12 Aug 2021 13:26:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 16 Mar 2021 13:07:46

Generated On: 12 Aug 2021 13:26:31

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 NOV 2020

US3752162

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

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

Visit date (dd MMM yyyy)	18 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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US3752162

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 15:21:44

Generated On: 12 Aug 2021 13:26:31

Date of updated informed consent (<i>dd MMM yyyy</i>)	18 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>)	18 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

US3752162

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

Height	172.2 cm
Weight	95.5 kg
BMI (xxx.x)	32.20602

US3752162

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

Height	172.2 cm
Weight	95.5 kg
BMI (xxx.x)	32.20602
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 JAN 2021
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 10:10
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3752162

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

Height	172.2 cm
Weight	95.5 kg
BMI (xxx.x)	32.20602
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 JAN 2021
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 11:16
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3752162

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

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3752162

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

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

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) 18 JAN 2021

What was the treatment time? (00:00-23:59) 10:46 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 10:46

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

US3752162

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

10:24 (24 HR)

Collection date and time (derived)

18 JAN 2021 10:24

US3752162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

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

Collection date (dd MMM yyyy)	18 JAN 2021
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Collection time (00:00 - 23:59)	10:27
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Collection Date and Time (derived)	18 JAN 2021 10:27
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US3752162

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

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:37:04

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag	1
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OLD29 Placebo Flag	1
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US3752162

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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	OLD29

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

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)	24 FEB 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 11:05
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 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)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

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)	24 FEB 2021
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 11:52
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3752162

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

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) 24 FEB 2021

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 11:22

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

US3752162

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:28:49

Generated On: 12 Aug 2021 13:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752162

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:28:49

Generated On: 12 Aug 2021 13:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752162

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:07 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 11:07
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752162

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3752162

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

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

Collection date (dd MMM yyyy)	24 MAR 2021
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Collection time (00:00-23:59)	11:15 (24 HR)
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Collection date and time (derived)	24 MAR 2021 11:15
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US3752162

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 18:37:02

Generated On: 12 Aug 2021 13:26:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

AEID

Adverse event

FRACTURED FOOT(RIGHT)

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 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 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 (1)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

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 <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 _____	
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)	_____

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

AEID	USA-US113-2020-MRNA-1273-P30 1000004
Adverse event	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)	17 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)	2 NOV 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 (2)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

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	KNOWN EXPOSURE 07OCT2020
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)	

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

AEID

Adverse event

LOW BACK PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 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)

15 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 (3)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

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 <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 _____	
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)	_____

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

AEID

Adverse event

MOTOR VEHICLE ACCIDENT

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 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

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 <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 _____	
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)	_____

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

AEID

Adverse event

CONTUSED RIGHT LUNG(FROM
MVA)

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 SEP 2020

Start time (00:00-23:59)

00:00 (24 HR)

AE start date and time (derived)

16 SEP 2020 00:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 NOV 2020

End time (00:00-23:59)

08:00 (24 HR)

AE End Date and Time (derived)

26 NOV 2020 08:00

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)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

AEID

Adverse event

SKIN LESIONS X2 TO RIGHT
LOWER EXTREMITY STATUS
POST POSSIBLE SPIDER BITES

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 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 (6)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

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 type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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 (7)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

AEID	
Adverse event	DEPRESSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (7)

Data signed: (b) (4) 27 Mar 2021 14:57:34

Generated On: 12 Aug 2021 13:26:31

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 <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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" 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)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 18:37:02

Generated On: 12 Aug 2021 13:26:31

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

Yes ☒

No ☐

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

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication PROSTATE ENLARGEMENT

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	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 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication TREAT POST-OPERATIVE PAIN

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 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)		23 OCT 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 (3)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication TREATMENT OF
POST-OPERATIVE PAIN FROM
LAMINECTOMY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	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)		15 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)		23 OCT 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 (4)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication ACETAMINOPHEN/DIPHENHYD
RAMINE

Prophylaxis Yes ☐
No ☒

Indication TREATMENT OF SYMPTOMS
RELATED COVID-19/SLEEP AID

Dose per administration 1000/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	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)	20 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)		20 OCT 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 (5)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication TREATMENT OF SYMPTOMS
RELATED TO COVID-19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	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)		17 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)		31 OCT 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 (6)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR DEEP
VENOUS THROMBOSIS
FOLLOWING LAMINECTOMY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	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)	20 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)	23 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication ZICAM COLD REMEDY/
ZINCUM ACETICUM/ZINCUM
GLUCONICUM

Prophylaxis Yes ☐
No ☒

Indication SHORTEN DURATION OF COVID
SYMPTOMS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	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)	22 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)	05 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 (8)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication SHORTEN
DURATION/DECREASE
SEVERITY OF SYMPTOMS
RELATED TO COVID-19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	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)	20 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)	05 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 (9)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication TREATMENT OF SYMPTOMS
RELATED TO COVID-19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 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)	05 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 (10)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication TREATMENT OF SYMPTOMS
RELATED TO COVID-19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 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)	05 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 (11)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication KEFLEX

Prophylaxis Yes ☐
No ☒

Indication POST OP MEDICATION AFTER
HEMILAMINECTOMY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Mar 2021 18:36:58

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	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)	15 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)	17 OCT 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 (12)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication ROBAXIN

Prophylaxis Yes ☐
No ☒

Indication POST OP MEDICATION AFTER
HEMILAMINECTOMY

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication POST OP PAIN AFTER
HEMILAMINECTOMY

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLAXIS
AFTER SURGERY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication INSECT BITES RIGHT LOWER
EXTREMITIES

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 JAN 2021	
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"/>

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

Name of Medication WELLBURTIN

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 25 Mar 2021 18:36:58

Generated On: 12 Aug 2021 13:26:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 18:37:02

Generated On: 12 Aug 2021 13:26:31

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Feb 2021 18:37:02

Generated On: 12 Aug 2021 13:26:31

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
15 OCT 2020	L5 S1 DISCECTOMY WITH RIGHT LATERAL HEMI LAMINECTOMY	Medical History	
30 SEP 2020	LUMBAR F/E X-RAY	Diagnostic	
02 SEP 2020	MRI LUMBAR W/O CONTRAST	Diagnostic	

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input type="checkbox"/>
	Visit 3 Day 57	<input checked="" type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	True
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	True
Vital Signs - Dosing	False
Physical Examination	True
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	True
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 06 Mar 2021 00:28:48

Generated On: 12 Aug 2021 13:26:31

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	21 OCT 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	True
Missed Assessment	True
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	True
Sponsor hold due to COVID-19	False
Participant decision	False

US3752162

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:26:31

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

US3752162

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:26:31

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

SAEID	USA-US113-2020-MRNA-1273-P301000004
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

SAEID	USA-US113-2020-MRNA-1273-P301000004
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	02/NOV/2020 14:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 18:37:03

Generated On: 12 Aug 2021 13:26:31

SAEID	USA-US113-2020-MRNA-1273-P301000004
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/NOV/2020 08:53
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

US3752162 (Prod: Baptist Health Center for Clinical Research)

US3752162

Form: Participant Creation

Generated On: 12 Aug 2021 13:26:31

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:18:13
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:17:43
User entered 'US3752162'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:34:26

US3752162

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:42:18

US3752162

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:34:27

US3752162

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:42:18

US3752162

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'SCRN'	System	19 Aug 2020 20:42:18

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:34:28

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '70'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'YEARS'	System	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '70'	System	19 Aug 2020 20:42:39

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:26:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:22

US3752162

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:26:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:42:39

US3752162

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Aug 2020'	System	19 Aug 2020 20:42:39

US3752162

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2020'	System	19 Aug 2020 20:42:39

US3752162

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:26:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:42:39

US3752162

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:42:39

US3752162

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:42:39

US3752162

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:26:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:42:39

US3752162

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:26:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:42:39

US3752162

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:26:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:34:27

US3752162

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:26:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'I'	System	19 Aug 2020 20:42:44

US3752162

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:42:44

US3752162

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:26:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:23:47

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual impairment, LLT: Visual disturbance - version MedDRA\23.0.	(b) (4)	20 Oct 2020 09:41:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 09:41:36
Data point term sent to Coder	(b) (4)	19 Oct 2020 13:55:48
User closed query 'Per CDM Coding: Multiple concepts are reported. Please split into separate records, e.g. one of VISION DISTURBANCE and one of WEARS GLASSES (UNKNOWN DIAGNOSIS)' (Site from System).	System	19 Oct 2020 13:55:02
Query 'Per CDM Coding: Multiple concepts are reported. Please split into separate records, e.g. one of VISION DISTURBANCE and one of WEARS GLASSES (UNKNOWN DIAGNOSIS)' answered with 'UPDATED' (Site from System).	System	
User entered 'VISION DISTURBANCE: (UNKNOWN DIAGNOSIS)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:55:02
User opened query 'Per CDM Coding: Multiple concepts are reported. Please split into separate records, e.g. one of VISION DISTURBANCE and one of WEARS GLASSES (UNKNOWN DIAGNOSIS)' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 13:54:56
Data point term sent to Coder	(b) (4), (b) (6)	19 Oct 2020 13:46:32
Coding entries removed.	Coder Import (b) (4)	19 Oct 2020 13:46:32
User entered 'VISION DISTURBANCE: WEARS GLASSES (unknown diagnosis)' reason for change: Data Entry Error	(b) (4)	
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Eyeglasses wearer - version MedDRA\23.0.	(b) (4), (b) (6)	16 Oct 2020 16:11:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4), (b) (6)	16 Oct 2020 16:11:18
	Coder Import (b) (4)	16 Oct 2020 16:11:18
	(b) (4)	20 Aug 2020 16:25:33
	Coder Import (b) (4)	20 Aug 2020 16:25:33
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	20 Aug 2020 16:24:58
User entered 'Vision disturbance: wears glasses'	(b) (4), (b) (6)	20 Aug 2020 16:24:14

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:24:14

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:24:14

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:24:14

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:24:14

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:24:14

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 1990'	System	20 Aug 2020 16:24:14

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '1990'	System	20 Aug 2020 16:24:14

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:24:14

US3752162

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:24:14

US3752162

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:26:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated triglycerides, PT: Hypertriglyceridaemia, LLT: Hypertriglyceridemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 16:25:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:25:34
Data point term sent to Coder	System	20 Aug 2020 16:25:01
User entered 'Hypertriglyceridemia'	(b) (4), (b) (6)	20 Aug 2020 16:24:49

US3752162

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 1976'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:24:49

US3752162

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:24:49

US3752162

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:24:49

US3752162

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:24:49

US3752162

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:24:49

US3752162

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 1976'	System	20 Aug 2020 16:24:49

US3752162

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '1976'	System	20 Aug 2020 16:24:49

US3752162

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:24:49

US3752162

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:24:49

US3752162

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4)	19 Oct 2020 19:16:05
' (Site from DM).	(b) (4), (b) (6)	
Query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	13 Oct 2020 13:20:15
' answered with 'unknown why there is no con med being taken for this condition' (Site from DM).		
User opened query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	12 Oct 2020 23:08:50
' (Site from DM).		
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 16:27:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	20 Aug 2020 16:27:22
Data point term sent to Coder	System	20 Aug 2020 16:26:04
User entered 'Asthma'	(b) (4), (b) (6)	20 Aug 2020 16:25:20

US3752162

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:25:20

US3752162

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:25:20

US3752162

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:25:20

US3752162

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:25:20

US3752162

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:25:20

US3752162

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2000'	System	20 Aug 2020 16:25:20

US3752162

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2000'	System	20 Aug 2020 16:25:20

US3752162

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:25:20

US3752162

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:25:20

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:16:12
' (Site from DM).		
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:22:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:22:36
Data point term sent to Coder	System	13 Oct 2020 13:21:15
Query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	13 Oct 2020 13:20:58
' answered with 'unknown why there is no con med for treatment of this condition' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	13 Oct 2020 13:20:43
User entered 'CHOLECYSTECTOMY (associated condition unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 13:20:43
User opened query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	12 Oct 2020 23:09:20
' (Site from DM).		

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:27:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:27:22
Data point term sent to Coder	System	20 Aug 2020 16:26:06
User entered 'Cholecystectomy'	(b) (4), (b) (6)	20 Aug 2020 16:25:38

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:25:38

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:25:38

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:25:38

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:25:38

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:25:38

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2013'	System	20 Aug 2020 16:25:38

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2013'	System	20 Aug 2020 16:25:38

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2013'	System	20 Aug 2020 16:25:38

US3752162

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2013'	System	20 Aug 2020 16:25:38

US3752162

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
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: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 16:27:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:27:22
Data point term sent to Coder	System	20 Aug 2020 16:26:07
User entered 'GERD/reflux'	(b) (4), (b) (6)	20 Aug 2020 16:26:00

US3752162

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:26:00

US3752162

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:26:00

US3752162

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:26:00

US3752162

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:26:00

US3752162

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:26:00

US3752162

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 1990'	System	20 Aug 2020 16:26:00

US3752162

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '1990'	System	20 Aug 2020 16:26:00

US3752162

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:26:00

US3752162

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:26:00

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin lesion removal, LLT: Skin lesion excision - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 18:06:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Nov 2020 18:06:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Skin cancer excision - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:57:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:57:51
Data point term sent to Coder	System	16 Oct 2020 16:12:05
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 16:11:57
User entered 'SKIN CANCER REMOVAL RIGHT HAND (unknown if benign or malignant)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:11:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Skin cancer excision - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 18:47:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 18:47:06
Data point term sent to Coder	System	20 Aug 2020 16:29:17
Coding entries removed.	(b) (4), (b) (6)	20 Aug 2020 16:28:36
User entered 'SKIN CANCER REMOVAL right hand' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:28:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Skin cancer excision - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 16:27:23

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Aug 2020 16:27:23
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 16:27:11
User entered 'Skin cancer removal'	(b) (4), (b) (6)	20 Aug 2020 16:26:43

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:26:43

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:26:43

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:26:43

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:26:43

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:26:43

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2020'	System	20 Aug 2020 16:26:43

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2020'	System	20 Aug 2020 16:26:43

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2020'	System	20 Aug 2020 16:26:43

US3752162

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2020'	System	20 Aug 2020 16:26:43

US3752162

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 16:27:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:27:23
Data point term sent to Coder	System	20 Aug 2020 16:27:11
User entered 'Low back pain'	(b) (4), (b) (6)	20 Aug 2020 16:27:01

US3752162

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:27:01

US3752162

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:27:01

US3752162

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:27:01

US3752162

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:27:01

US3752162

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:27:01

US3752162

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2015'	System	20 Aug 2020 16:27:01

US3752162

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2015'	System	20 Aug 2020 16:27:01

US3752162

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:27:01

US3752162

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:27:01

US3752162

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:26:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
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.	(b) (4) Coder Import	20 Aug 2020 16:29:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4) Coder Import	20 Aug 2020 16:29:25
Data point term sent to Coder	System	20 Aug 2020 16:28:13
User entered 'Vertigo'	(b) (4), (b) (6)	20 Aug 2020 16:27:17

US3752162

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:27:17

US3752162

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:27:17

US3752162

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:27:17

US3752162

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:27:17

US3752162

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:27:17

US3752162

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2019'	System	20 Aug 2020 16:27:17

US3752162

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2019'	System	20 Aug 2020 16:27:17

US3752162

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:27:17

US3752162

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:27:17

US3752162

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 09:59:21
Data point term sent to Coder	(b) (4)	
User entered 'Prostate enlargement'	Coder Import (b) (4)	21 Aug 2020 09:59:21
	(b) (4)	
	System	20 Aug 2020 16:28:15
	(b) (4), (b) (6)	20 Aug 2020 16:28:00

US3752162

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:28:00

US3752162

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:28:00

US3752162

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:28:00

US3752162

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:28:00

US3752162

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:28:00

US3752162

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2020'	System	20 Aug 2020 16:28:00

US3752162

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2020'	System	20 Aug 2020 16:28:00

US3752162

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:28:00

US3752162

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	20 Aug 2020 16:28:00

US3752162

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:38:33
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:06:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:06:31
Query 'Per MM, please include the underlying condition that led to the procedure. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:16:47
Data point term sent to Coder	System	05 Oct 2020 15:16:43
Coding entries removed.	(b) (4), (b) (6)	05 Oct 2020 15:16:41
User entered 'COLONOSCOPY (underlying condition unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:16:41
User opened query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 02:33:58
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:31:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:31:23
Data point term sent to Coder	System	20 Aug 2020 16:30:21
User entered 'Colonoscopy'	(b) (4), (b) (6)	20 Aug 2020 16:29:22

US3752162

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:29:22

US3752162

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:29:22

US3752162

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:29:22

US3752162

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:29:22

US3752162

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:29:22

US3752162

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 1985'	System	20 Aug 2020 16:29:22

US3752162

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '1985'	System	20 Aug 2020 16:29:22

US3752162

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 1985'	System	20 Aug 2020 16:29:22

US3752162

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '1985'	System	20 Aug 2020 16:29:22

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	(b) (4)	09 Nov 2020 14:17:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 14:17:33
Data point term sent to Coder	System	09 Nov 2020 14:17:01
User closed query 'For coding purposes, please split BILATERAL CATARACT SURGERY into separate entries. 1. BILATERAL CATARACT and 2. BILATERAL CATARACT SURGERY' (Site from System).	System	09 Nov 2020 14:16:44
Query 'For coding purposes, please split BILATERAL CATARACT SURGERY into separate entries. 1. BILATERAL CATARACT and 2. BILATERAL CATARACT SURGERY' answered with 'updated' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 14:16:44
Coding entries removed.	(b) (4), (b) (6)	09 Nov 2020 14:16:38
User entered 'BILATERAL CATARACTs' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 14:16:38
User opened query 'For coding purposes, please split BILATERAL CATARACT SURGERY into separate entries. 1. BILATERAL CATARACT and 2. BILATERAL CATARACT SURGERY' (Site from System).	Coder Import (b) (4)	08 Nov 2020 18:03:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 21:59:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 21:59:48

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:31:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:31:23
Data point term sent to Coder	System	20 Aug 2020 16:30:23
User entered 'Bilateral cataract surgery'	(b) (4), (b) (6) (b) (4)	20 Aug 2020 16:30:07

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:30:07

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:30:07

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:30:07

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:30:07

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:30:07

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2018'	System	20 Aug 2020 16:30:07

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2018'	System	20 Aug 2020 16:30:07

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2018'	System	20 Aug 2020 16:30:07

US3752162

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2018'	System	20 Aug 2020 16:30:07

US3752162

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Eyeglasses wearer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Oct 2020 13:56:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 13:56:34
Data point term sent to Coder	System	19 Oct 2020 13:55:48
User entered 'WEARS GLASSES (UNKNOWN DIAGNOSIS)'	(b) (4), (b) (6)	19 Oct 2020 13:55:28

US3752162

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'UN UNK 1990'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:55:28

US3752162

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:55:28

US3752162

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:55:28

US3752162

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:55:28

US3752162

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:55:28

US3752162

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 1990'	System	19 Oct 2020 13:55:28

US3752162

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '1990'	System	19 Oct 2020 13:55:28

US3752162

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	19 Oct 2020 13:55:28

US3752162

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	19 Oct 2020 13:55:28

US3752162

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:26:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 14:18:34
Data point term sent to Coder	(b) (4)	
User entered 'Bilateral cataract surgery'	Coder Import (b) (4)	09 Nov 2020 14:18:34
	(b) (4)	
	System	09 Nov 2020 14:18:02
	(b) (4), (b) (6)	09 Nov 2020 14:17:04

US3752162

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:17:04

US3752162

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:17:04

US3752162

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:17:04

US3752162

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:17:04

US3752162

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:17:04

US3752162

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2018'	System	09 Nov 2020 14:17:04

US3752162

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2018'	System	09 Nov 2020 14:17:04

US3752162

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Jan 2018'	System	09 Nov 2020 14:17:04

US3752162

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2018'	System	09 Nov 2020 14:17:04

US3752162

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit hyperactivity disorder - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:47:42
Data point term sent to Coder	(b) (4)	
User entered 'ATTENTION DEFICIT DISORDER WITHOUT HYPERACTIVITY' reason for change:	Coder Import (b) (4)	10 Nov 2020 21:47:42
Data Entry Error	(b) (4)	
User entered 'ATTENTION DEFICIT DISORDER'	System	10 Nov 2020 17:58:44
	Haylee Rowe (b) (4)	10 Nov 2020 17:58:22
	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 17:57:54
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '13 Oct 2017' reason for change: Data Entry Error	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 18:09:50
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 17:57:54
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 18:09:50
User entered '1'	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 17:57:54
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:57:54

US3752162

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	10 Nov 2020 17:57:54
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 17:57:54
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'Oct 2017'	System	10 Nov 2020 18:09:50
User entered empty.	System	10 Nov 2020 17:57:54

US3752162

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2017'	System	10 Nov 2020 18:09:50
User entered empty.	System	10 Nov 2020 17:57:54

US3752162

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 17:57:54

US3752162

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 17:57:54

US3752162

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Metabolic and nutritional disorders congenital, HLT: Inborn errors of bilirubin metabolism, PT: Gilbert's syndrome, LLT: Gilbert's syndrome - version MedDRA\\23.0.	(b) (4) Coder Import	10 Nov 2020 18:01:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4) Coder Import	10 Nov 2020 18:01:37
Data point term sent to Coder	System	10 Nov 2020 18:00:45
User entered 'GILBERT'S SYNDROME'	Haylee Rowe	10 Nov 2020 18:00:39
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '16 May 2018' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 18:08:59
User entered empty.	Haylee Rowe	10 Nov 2020 18:00:39
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 18:08:59
User entered '1'	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 18:00:39
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 18:00:39

US3752162

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	10 Nov 2020 18:00:39
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 18:00:39
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'May 2018'	System	10 Nov 2020 18:08:59
User entered empty.	System	10 Nov 2020 18:00:39

US3752162

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2018'	System	10 Nov 2020 18:08:59
User entered empty.	System	10 Nov 2020 18:00:39

US3752162

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:00:39

US3752162

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:00:39

US3752162

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:36:42
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Jamie Pettus Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4)	21 Jan 2021 16:29:28
' answered with 'This is an intermittent condition and episodes often last less than 24 hours at a time and do not require treatment' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	18 Jan 2021 02:39:30
' (Site from DM).		
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 18:08:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 18:08:38
Data point term sent to Coder	System	10 Nov 2020 18:08:06
User entered 'PAROXYSMAL ATRIAL FIBRILLATION'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 18:07:12

US3752162

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '16 May 2020'	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 18:07:12
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 18:07:12

US3752162

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 18:07:12

US3752162

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 18:07:12
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 18:07:12

US3752162

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'May 2020'	System	10 Nov 2020 18:07:12

US3752162

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '2020'	System	10 Nov 2020 18:07:12

US3752162

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:07:12

US3752162

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:07:12

US3752162

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:26:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	(b) (4) Coder Import	10 Nov 2020 18:18:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4) Coder Import	10 Nov 2020 18:18:38
Data point term sent to Coder	System	10 Nov 2020 18:17:24
User entered 'VASECTOMY'	Haylee Rowe	10 Nov 2020 18:16:41
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	10 Nov 2020 18:16:41
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'I'	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 18:16:41
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 18:16:41
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	10 Nov 2020 18:16:41
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'I'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 18:16:41

US3752162

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:16:41

US3752162

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:16:41

US3752162

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:16:41

US3752162

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:16:41

US3752162

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:26:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 18:18:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 18:18:38
Data point term sent to Coder	System	10 Nov 2020 18:18:26
User entered 'ROTATOR CUFF REPAIR'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 18:18:25

US3752162

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	10 Nov 2020 18:18:25
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'I'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 18:18:25

US3752162

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 18:18:25

US3752162

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	10 Nov 2020 18:18:25
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'I'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 18:18:25

US3752162

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:18:25

US3752162

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:18:25

US3752162

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:18:25

US3752162

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	10 Nov 2020 18:18:25

US3752162

Folder: Screening

Form: Medical History (19)

Generated On: 12 Aug 2021 13:26:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
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.	(b) (4) Coder Import (b) (4)	11 Jan 2021 21:02:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Jan 2021 21:02:43
Data point term sent to Coder	System	11 Jan 2021 21:02:12
User entered 'seasonal allergies'	Jamie Pettus (b) (4)	11 Jan 2021 21:01:34
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (19)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 21:01:34

US3752162

Folder: Screening

Form: Medical History (19)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'I'	(b) (4) Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 21:01:34

US3752162

Folder: Screening

Form: Medical History (19)

Generated On: 12 Aug 2021 13:26:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	11 Jan 2021 21:01:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	11 Jan 2021 21:01:57
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	11 Jan 2021 21:01:34
User entered 'No (N)'	System	11 Jan 2021 21:01:34
	Jamie Pettus (b) (4)	11 Jan 2021 21:01:34
	(b) (4)	

US3752162

Folder: Screening

Form: Medical History (19)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 21:01:34

US3752162

Folder: Screening

Form: Medical History (19)

Generated On: 12 Aug 2021 13:26:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 21:01:34

US3752162

Folder: Screening

Form: Medical History (19)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	11 Jan 2021 21:01:34

US3752162

Folder: Screening

Form: Medical History (19)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	11 Jan 2021 21:01:34

US3752162

Folder: Screening

Form: Medical History (19)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	11 Jan 2021 21:01:34

US3752162

Folder: Screening

Form: Medical History (19)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered empty.	System	11 Jan 2021 21:01:34

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '14:40'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered '19 Aug 2020 14:40'	System	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '68.0' in	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:31:04
DataPoint set to visible.	System	19 Aug 2020 20:42:44

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '209.0' lb	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:31:04
DataPoint set to visible.	System	19 Aug 2020 20:42:44

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
Amendment Manager: User entered '31.84479'	System	17 Sep 2020 00:14:50
User entered '31.8'	System	20 Aug 2020 16:31:04
DataPoint set to visible.	System	19 Aug 2020 20:42:44

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'kg/m2'	System	20 Aug 2020 16:31:04
DataPoint set to visible.	System	19 Aug 2020 20:42:44

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per CDM: units of measure should not be recorded if value is blank or ND. Please update the unit of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 09:18:14
Query 'Per CDM: units of measure should not be recorded if value is blank or ND. Please update the unit of measure by selecting ... in the drop down box provided. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:36:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:36:21
User opened query 'Per CDM: units of measure should not be recorded if value is blank or ND. Please update the unit of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 15:36:19
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 20:40:28
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:28:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 13:27:57
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 08:01:47
User entered '97.8' F	(b) (4), (b) (6)	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:17:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:27:57
User entered '60'	(b) (4), (b) (6)	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'bpm'	System	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:27:57
User entered '20'	(b) (4), (b) (6)	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'breaths/min'	System	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:27:57
User entered '118'	(b) (4), (b) (6)	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'mmHg'	System	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:27:57
User entered '062'	(b) (4), (b) (6)	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User entered 'mmHg'	System	20 Aug 2020 16:31:04

US3752162

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26

US3752162

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:26:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:17:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:31:13

US3752162

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:26:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:17:21
User entered '19 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 16:31:13

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:26:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:08

US3752162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:32

US3752162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:32

US3752162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:32:32

US3752162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'VISIT1'	System	20 Aug 2020 16:32:32

US3752162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:14:35

US3752162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:26:31

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 05:41:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:41:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 20:14:35
User entered '187139' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:14:35

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:26:31

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:14:35

US3752162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:26:31

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:33:02

US3752162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:26:31

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:33:02

US3752162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:26:31

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:33:02

US3752162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:26:31

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:33:02

US3752162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:26:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:33:02

US3752162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:26:31

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:12:28
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:13
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:36:53

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:10
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:15:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 14:15:44
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:44:49
User entered '68.0' in	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:15:44
User entered '209.0' lb	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:10
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:15:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 14:15:44
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:44:49
User entered '68.0' in	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:15:44
User entered '209.0' lb	(b) (4), (b) (6)	20 Aug 2020 16:34:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:34:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:34:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '14:40'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:34:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '19 Aug 2020 14:40'	System	20 Aug 2020 16:34:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:34:49
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:34:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 16:34:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	20 Aug 2020 16:34:49
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:34:49
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'bpm'	System	20 Aug 2020 16:34:49
User entered empty.	System	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 16:34:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	20 Aug 2020 16:34:49
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:34:49
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'breaths/min'	System	20 Aug 2020 16:34:49
User entered empty.	System	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 16:34:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	20 Aug 2020 16:34:49
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:34:49
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'mmHg'	System	20 Aug 2020 16:34:49
User entered empty.	System	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 16:34:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	20 Aug 2020 16:34:49
User entered '062' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:34:49
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'mmHg'	System	20 Aug 2020 16:34:49
User entered empty.	System	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:10
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:15:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 14:15:44
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:44:49
User entered '68.0' in	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:15:44
User entered '209.0' lb	(b) (4), (b) (6)	20 Aug 2020 16:34:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:41:38
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 16:34:12
User entered '16:10'	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '19 Aug 2020 16:10'	System	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 16:35:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:35:31
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 16:35:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	20 Aug 2020 16:35:31
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:35:31
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'bpm'	System	20 Aug 2020 16:35:31
User entered empty.	System	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 16:35:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	20 Aug 2020 16:35:31
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:35:31
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'breaths/min'	System	20 Aug 2020 16:35:31
User entered empty.	System	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 16:35:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	20 Aug 2020 16:35:31
User entered '124' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:35:31
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'mmHg'	System	20 Aug 2020 16:35:31
User entered empty.	System	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 16:35:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	20 Aug 2020 16:35:31
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 16:35:31
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'mmHg'	System	20 Aug 2020 16:35:31
User entered empty.	System	20 Aug 2020 16:34:12

US3752162

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:23:27
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 13:50:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 13:50:34
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 20:47:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:35:42

US3752162

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 13:50:34
User entered '19 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 16:35:42

US3752162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:43:09

US3752162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:43:09

US3752162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:43:09

US3752162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 20:43:09

US3752162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:43:09

US3752162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '15:34'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:43:09

US3752162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '19 Aug 2020 15:34'	System	19 Aug 2020 20:43:09

US3752162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:43:09

US3752162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'ONCE'	System	19 Aug 2020 20:43:09

US3752162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 20:43:09

US3752162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:36:31

US3752162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:36:31

US3752162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '14:50'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:36:31

US3752162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '19 Aug 2020 14:50'	System	20 Aug 2020 16:36:31

US3752162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:36:46

US3752162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:26:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	20 Aug 2020 16:36:46

US3752162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:36:46

US3752162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:26:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '14:47'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:36:46

US3752162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:26:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '19 Aug 2020 14:47'	System	20 Aug 2020 16:36:46

US3752162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:26:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	20 Aug 2020 16:36:46

US3752162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:36:46

US3752162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:26:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:36:46

US3752162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:26:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered empty.	System	20 Aug 2020 16:36:46

US3752162

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 16:36:52

US3752162

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'I'	System	20 Aug 2020 16:36:52

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T15:58:06', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '72161c48-ceee-4589-986f-0ff1ea977691' User entered 'Yes (Y)'	System	19 Aug 2020 20:58:36
	System	19 Aug 2020 20:58:36

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T15:58:16', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '72161c48-ceee-4589-986f-0ff1ea977691' User entered '98.0'	System	19 Aug 2020 20:58:36
	System	19 Aug 2020 20:58:36

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T15:58:21', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '72161c48-ceee-4589-986f-0ff1ea977691'	System	19 Aug 2020 20:58:36
User entered 'No (N)'	System	19 Aug 2020 20:58:36

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T15:58:33', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '72161c48-ceee-4589-986f-0ff1ea977691' User entered '19 Aug 2020 15:58'	System	19 Aug 2020 20:58:36
	System	19 Aug 2020 20:58:36

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Aug 2020 15:54'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Aug 2020 18:24'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:21:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '80fccf15-8ed8-49be-b920-a14f955ace95'	System	20 Aug 2020 00:22:15
User entered 'Yes (Y)'	System	20 Aug 2020 00:22:15

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:21:57', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '80fccf15-8ed8-49be-b920-a14f955ace95' User entered '98.8'	System	20 Aug 2020 00:22:15
	System	20 Aug 2020 00:22:15

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:22:01', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '80fccf15-8ed8-49be-b920-a14f955ace95'	System	20 Aug 2020 00:22:15
User entered 'No (N)'	System	20 Aug 2020 00:22:15

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:22:13', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '80fccf15-8ed8-49be-b920-a14f955ace95' User entered '19 Aug 2020 19:22'	System	20 Aug 2020 00:22:15
	System	20 Aug 2020 00:22:15

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Aug 2020 19:19'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 2'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:37:22', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '970d2638-4cb6-45b4-b92f-d6825fa391c0'	System	21 Aug 2020 00:37:49
User entered 'No (N)'	System	21 Aug 2020 00:37:49

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:37:32', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '970d2638-4cb6-45b4-b92f-d6825fa391c0'	System	21 Aug 2020 00:37:49
User entered 'No (N)'	System	21 Aug 2020 00:37:49

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:37:45', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '970d2638-4cb6-45b4-b92f-d6825fa391c0'	System	21 Aug 2020 00:37:49
User entered '20 Aug 2020 19:37'	System	21 Aug 2020 00:37:49

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 3'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:41:27', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2ba8fccf-6107-47c1-8061-c6255a2f2ca2'	System	21 Aug 2020 22:41:48
User entered 'Yes (Y)'	System	21 Aug 2020 22:41:48

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:41:34', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2ba8fccf-6107-47c1-8061-c6255a2f2ca2'	System	21 Aug 2020 22:41:48
User entered '98.6'	System	21 Aug 2020 22:41:48

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:41:39', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2ba8fccf-6107-47c1-8061-c6255a2f2ca2'	System	21 Aug 2020 22:41:48
User entered 'No (N)'	System	21 Aug 2020 22:41:48

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:41:44', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2ba8fccf-6107-47c1-8061-c6255a2f2ca2'	System	21 Aug 2020 22:41:48
User entered '21 Aug 2020 17:41'	System	21 Aug 2020 22:41:48

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 4'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:38:32', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '4a7f3367-8f45-44e3-8247-df72b1516bdb' User entered 'Yes (Y)'	System	23 Aug 2020 03:39:49
	System	23 Aug 2020 03:39:49

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:39:34', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '4a7f3367-8f45-44e3-8247-df72b1516bdb' User entered '97.9'	System	23 Aug 2020 03:39:49
	System	23 Aug 2020 03:39:49

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:39:40', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '4a7f3367-8f45-44e3-8247-df72b1516bdb' User entered 'No (N)'	System	23 Aug 2020 03:39:49
	System	23 Aug 2020 03:39:49

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:39:47', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '4a7f3367-8f45-44e3-8247-df72b1516bdb' User entered '22 Aug 2020 22:39'	System	23 Aug 2020 03:39:49
	System	23 Aug 2020 03:39:49

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 5'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:31:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7d213a06-588f-4408-86b0-f30219f97421' User entered 'Yes (Y)'	System	24 Aug 2020 13:32:11
	System	24 Aug 2020 13:32:11

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:31:54', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7d213a06-588f-4408-86b0-f30219f97421' User entered '96.7'	System	24 Aug 2020 13:32:11
	System	24 Aug 2020 13:32:11

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:02', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7d213a06-588f-4408-86b0-f30219f97421'	System	24 Aug 2020 13:32:11
User entered 'No (N)'	System	24 Aug 2020 13:32:11

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:08', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7d213a06-588f-4408-86b0-f30219f97421' User entered '24 Aug 2020 08:32'	System	24 Aug 2020 13:32:11
	System	24 Aug 2020 13:32:11

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 6'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:35:33', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '23810ffb-513c-493d-b9f1-55f709807a6b' User entered 'Yes (Y)'	System	25 Aug 2020 14:35:57
	System	25 Aug 2020 14:35:57

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:35:40', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '23810ffb-513c-493d-b9f1-55f709807a6b' User entered '97.4'	System	25 Aug 2020 14:35:57
	System	25 Aug 2020 14:35:57

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:35:45', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '23810ffb-513c-493d-b9f1-55f709807a6b'	System	25 Aug 2020 14:35:57
User entered 'No (N)'	System	25 Aug 2020 14:35:57

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:35:51', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '23810ffb-513c-493d-b9f1-55f709807a6b' User entered '25 Aug 2020 09:35'	System	25 Aug 2020 14:35:57
	System	25 Aug 2020 14:35:57

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 7'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:02:43', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e7ce521a-09ce-45cf-8114-4b6634d60dd3'	System	19 Aug 2020 21:03:52
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 21:03:52

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:02:47', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e7ce521a-09ce-45cf-8114-4b6634d60dd3'	System	19 Aug 2020 21:03:52
User entered 'No (N)'	System	19 Aug 2020 21:03:52

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:02:55', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e7ce521a-09ce-45cf-8114-4b6634d60dd3'	System	19 Aug 2020 21:03:52
User entered 'No (N)'	System	19 Aug 2020 21:03:52

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:03:03', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e7ce521a-09ce-45cf-8114-4b6634d60dd3'	System	19 Aug 2020 21:03:52
User entered 'None (1)'	System	19 Aug 2020 21:03:52

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:03:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e7ce521a-09ce-45cf-8114-4b6634d60dd3'	System	19 Aug 2020 21:03:52
User entered '19 Aug 2020 16:03'	System	19 Aug 2020 21:03:52

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Aug 2020 15:54'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Aug 2020 18:24'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:22:25', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '1f36ef15-8c0c-48a9-af26-604b3802886a'	System	20 Aug 2020 00:22:49
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 00:22:49

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:22:29', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '1f36ef15-8c0c-48a9-af26-604b3802886a'	System	20 Aug 2020 00:22:49
User entered 'No (N)'	System	20 Aug 2020 00:22:49

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:22:34', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '1f36ef15-8c0c-48a9-af26-604b3802886a'	System	20 Aug 2020 00:22:49
User entered 'No (N)'	System	20 Aug 2020 00:22:49

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:22:42', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '1f36ef15-8c0c-48a9-af26-604b3802886a'	System	20 Aug 2020 00:22:49
User entered 'None (1)'	System	20 Aug 2020 00:22:49

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:22:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '1f36ef15-8c0c-48a9-af26-604b3802886a' User entered '19 Aug 2020 19:22'	System	20 Aug 2020 00:22:49
	System	20 Aug 2020 00:22:49

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Aug 2020 19:19'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 2'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:39:21', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f6d872b9-4522-48eb-85b5-4d2fe7ffee69'	System	21 Aug 2020 00:41:02
User entered 'None (1)'	System	21 Aug 2020 00:41:02

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:40:10', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f6d872b9-4522-48eb-85b5-4d2fe7ffee69' User entered 'No (N)'	System	21 Aug 2020 00:41:02
	System	21 Aug 2020 00:41:02

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:40:16', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f6d872b9-4522-48eb-85b5-4d2fe7ffee69' User entered 'No (N)'	System	21 Aug 2020 00:41:02
	System	21 Aug 2020 00:41:02

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:40:32', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f6d872b9-4522-48eb-85b5-4d2fe7ffee69'	System	21 Aug 2020 00:41:02
User entered 'None (1)'	System	21 Aug 2020 00:41:02

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:40:58', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f6d872b9-4522-48eb-85b5-4d2fe7ffee69' User entered '20 Aug 2020 19:40'	System	21 Aug 2020 00:41:02
	System	21 Aug 2020 00:41:02

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 3'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:40:43', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'c0f4f171-4f00-4af6-bd83-1b27b97f377d'	System	21 Aug 2020 22:41:06
User entered 'None (1)'	System	21 Aug 2020 22:41:06

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:40:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'c0f4f171-4f00-4af6-bd83-1b27b97f377d'	System	21 Aug 2020 22:41:06
User entered 'No (N)'	System	21 Aug 2020 22:41:06

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:40:53', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'c0f4f171-4f00-4af6-bd83-1b27b97f377d'	System	21 Aug 2020 22:41:06
User entered 'No (N)'	System	21 Aug 2020 22:41:06

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:40:57', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'c0f4f171-4f00-4af6-bd83-1b27b97f377d'	System	21 Aug 2020 22:41:06
User entered 'None (1)'	System	21 Aug 2020 22:41:06

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:41:02', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'c0f4f171-4f00-4af6-bd83-1b27b97f377d' User entered '21 Aug 2020 17:41'	System	21 Aug 2020 22:41:06
	System	21 Aug 2020 22:41:06

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 4'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:39:52', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '995bcbc2-6d60-401a-9230-a856a68d1042'	System	23 Aug 2020 03:40:10
User entered 'None (1)'	System	23 Aug 2020 03:40:10

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:39:56', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '995bcbc2-6d60-401a-9230-a856a68d1042'	System	23 Aug 2020 03:40:10
User entered 'No (N)'	System	23 Aug 2020 03:40:10

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '995bcbc2-6d60-401a-9230-a856a68d1042'	System	23 Aug 2020 03:40:10
User entered 'No (N)'	System	23 Aug 2020 03:40:10

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:04', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '995bcbc2-6d60-401a-9230-a856a68d1042'	System	23 Aug 2020 03:40:10
User entered 'None (1)'	System	23 Aug 2020 03:40:10

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:08', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '995bcbc2-6d60-401a-9230-a856a68d1042'	System	23 Aug 2020 03:40:10
User entered '22 Aug 2020 22:40'	System	23 Aug 2020 03:40:10

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 5'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:27', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e0d7de85-b3ce-4992-9d7b-c68a2e7be0d7'	System	24 Aug 2020 13:32:45
User entered 'None (1)'	System	24 Aug 2020 13:32:45

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:25', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e0d7de85-b3ce-4992-9d7b-c68a2e7be0d7'	System	24 Aug 2020 13:32:45
User entered 'No (N)'	System	24 Aug 2020 13:32:45

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:31', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e0d7de85-b3ce-4992-9d7b-c68a2e7be0d7'	System	24 Aug 2020 13:32:45
User entered 'No (N)'	System	24 Aug 2020 13:32:45

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:34', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e0d7de85-b3ce-4992-9d7b-c68a2e7be0d7' User entered 'None (1)'	System	24 Aug 2020 13:32:45
	System	24 Aug 2020 13:32:45

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:40', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e0d7de85-b3ce-4992-9d7b-c68a2e7be0d7'	System	24 Aug 2020 13:32:45
User entered '24 Aug 2020 08:32'	System	24 Aug 2020 13:32:45

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 6'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:35:56', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '253d5c37-9907-4dd1-b5e7-beb5e2e66740'	System	25 Aug 2020 14:36:11
User entered 'None (1)'	System	25 Aug 2020 14:36:11

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:35:59', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '253d5c37-9907-4dd1-b5e7-beb5e2e66740' User entered 'No (N)'	System	25 Aug 2020 14:36:11
	System	25 Aug 2020 14:36:11

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:02', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '253d5c37-9907-4dd1-b5e7-beb5e2e66740' User entered 'No (N)'	System	25 Aug 2020 14:36:11
	System	25 Aug 2020 14:36:11

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:05', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '253d5c37-9907-4dd1-b5e7-beb5e2e66740'	System	25 Aug 2020 14:36:11
User entered 'None (1)'	System	25 Aug 2020 14:36:11

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:08', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '253d5c37-9907-4dd1-b5e7-beb5e2e66740' User entered '25 Aug 2020 09:36'	System	25 Aug 2020 14:36:11
	System	25 Aug 2020 14:36:11

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 7'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:04:18', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7698fdab-8ac0-4dfe-91b3-3e8580ca7504' User entered 'None (0)'	System	19 Aug 2020 21:05:19
	System	19 Aug 2020 21:05:19

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:04:22', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7698fdab-8ac0-4dfe-91b3-3e8580ca7504' User entered 'None (0)'	System	19 Aug 2020 21:05:19
	System	19 Aug 2020 21:05:19

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:04:27', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7698fdab-8ac0-4dfe-91b3-3e8580ca7504' User entered 'None (0)'	System	19 Aug 2020 21:05:19
	System	19 Aug 2020 21:05:19

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:04:32', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7698fdab-8ac0-4dfe-91b3-3e8580ca7504' User entered 'None (0)'	System	19 Aug 2020 21:05:19
	System	19 Aug 2020 21:05:19

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:04:40', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7698fdab-8ac0-4dfe-91b3-3e8580ca7504' User entered 'None (0)'	System	19 Aug 2020 21:05:19
	System	19 Aug 2020 21:05:19

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:04:45', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7698fdab-8ac0-4dfe-91b3-3e8580ca7504' User entered 'None (0)'	System	19 Aug 2020 21:05:19
	System	19 Aug 2020 21:05:19

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:04:55', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7698fdab-8ac0-4dfe-91b3-3e8580ca7504'	System	19 Aug 2020 21:05:19
User entered 'No (N)'	System	19 Aug 2020 21:05:19

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T16:05:14', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7698fdab-8ac0-4dfe-91b3-3e8580ca7504'	System	19 Aug 2020 21:05:19
User entered '19 Aug 2020 16:05'	System	19 Aug 2020 21:05:19

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Aug 2020 15:54'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Aug 2020 18:24'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:23:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '62697b96-c1de-42a4-820d-7eaf8d64d366'	System	20 Aug 2020 00:23:43
User entered 'None (0)'	System	20 Aug 2020 00:23:43

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:23:05', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '62697b96-c1de-42a4-820d-7eaf8d64d366'	System	20 Aug 2020 00:23:43
User entered 'None (0)'	System	20 Aug 2020 00:23:43

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:23:10', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '62697b96-c1de-42a4-820d-7eaf8d64d366' User entered 'None (0)'	System	20 Aug 2020 00:23:43
	System	20 Aug 2020 00:23:43

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:23:16', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '62697b96-c1de-42a4-820d-7eaf8d64d366' User entered 'None (0)'	System	20 Aug 2020 00:23:43
	System	20 Aug 2020 00:23:43

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:23:19', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '62697b96-c1de-42a4-820d-7eaf8d64d366'	System	20 Aug 2020 00:23:43
User entered 'None (0)'	System	20 Aug 2020 00:23:43

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:23:22', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '62697b96-c1de-42a4-820d-7eaf8d64d366'	System	20 Aug 2020 00:23:43
User entered 'None (0)'	System	20 Aug 2020 00:23:43

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:23:34', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '62697b96-c1de-42a4-820d-7eaf8d64d366'	System	20 Aug 2020 00:23:43
User entered 'No (N)'	System	20 Aug 2020 00:23:43

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-19T19:23:38', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '62697b96-c1de-42a4-820d-7eaf8d64d366'	System	20 Aug 2020 00:23:43
User entered '19 Aug 2020 19:23'	System	20 Aug 2020 00:23:43

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Aug 2020 19:19'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 2'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:37:56', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '83f57320-57cf-47e3-bb55-70becf48c346'	System	21 Aug 2020 00:39:08
User entered 'None (0)'	System	21 Aug 2020 00:39:08

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:38:08', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '83f57320-57cf-47e3-bb55-70becf48c346'	System	21 Aug 2020 00:39:08
User entered 'None (0)'	System	21 Aug 2020 00:39:08

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:38:17', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '83f57320-57cf-47e3-bb55-70becf48c346'	System	21 Aug 2020 00:39:08
User entered 'None (0)'	System	21 Aug 2020 00:39:08

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:38:25', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '83f57320-57cf-47e3-bb55-70becf48c346'	System	21 Aug 2020 00:39:08
User entered 'None (0)'	System	21 Aug 2020 00:39:08

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:38:39', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '83f57320-57cf-47e3-bb55-70becf48c346'	System	21 Aug 2020 00:39:08
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Aug 2020 00:39:08

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:38:43', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '83f57320-57cf-47e3-bb55-70becf48c346' User entered 'None (0)'	System	21 Aug 2020 00:39:08
	System	21 Aug 2020 00:39:08

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:38:52', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '83f57320-57cf-47e3-bb55-70becf48c346'	System	21 Aug 2020 00:39:08
User entered 'No (N)'	System	21 Aug 2020 00:39:08

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-20T19:39:07', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '83f57320-57cf-47e3-bb55-70becf48c346'	System	21 Aug 2020 00:39:08
User entered '20 Aug 2020 19:39'	System	21 Aug 2020 00:39:08

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 3'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:41:50', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '95e33e19-3843-404d-ba0e-2722632afd7a' User entered 'None (0)'	System	21 Aug 2020 22:42:20
	System	21 Aug 2020 22:42:20

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:41:54', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '95e33e19-3843-404d-ba0e-2722632afd7a' User entered 'None (0)'	System	21 Aug 2020 22:42:20
	System	21 Aug 2020 22:42:20

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:41:58', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '95e33e19-3843-404d-ba0e-2722632afd7a' User entered 'None (0)'	System	21 Aug 2020 22:42:20
	System	21 Aug 2020 22:42:20

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:42:01', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '95e33e19-3843-404d-ba0e-2722632afd7a' User entered 'None (0)'	System	21 Aug 2020 22:42:20
	System	21 Aug 2020 22:42:20

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:42:05', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '95e33e19-3843-404d-ba0e-2722632afd7a' User entered 'None (0)'	System	21 Aug 2020 22:42:20
	System	21 Aug 2020 22:42:20

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:42:08', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '95e33e19-3843-404d-ba0e-2722632afd7a' User entered 'None (0)'	System	21 Aug 2020 22:42:20
	System	21 Aug 2020 22:42:20

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:42:13', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '95e33e19-3843-404d-ba0e-2722632afd7a' User entered 'No (N)'	System	21 Aug 2020 22:42:20
	System	21 Aug 2020 22:42:20

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-21T17:42:16', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '95e33e19-3843-404d-ba0e-2722632afd7a' User entered '21 Aug 2020 17:42'	System	21 Aug 2020 22:42:20
	System	21 Aug 2020 22:42:20

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 4'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:13', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'd0bb7e21-436f-4789-820a-77e491642087' User entered 'None (0)'	System	23 Aug 2020 03:40:36
	System	23 Aug 2020 03:40:36

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:16', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'd0bb7e21-436f-4789-820a-77e491642087' User entered 'None (0)'	System	23 Aug 2020 03:40:36
	System	23 Aug 2020 03:40:36

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:19', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'd0bb7e21-436f-4789-820a-77e491642087' User entered 'None (0)'	System	23 Aug 2020 03:40:36
	System	23 Aug 2020 03:40:36

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:22', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'd0bb7e21-436f-4789-820a-77e491642087' User entered 'None (0)'	System	23 Aug 2020 03:40:36
	System	23 Aug 2020 03:40:36

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:25', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'd0bb7e21-436f-4789-820a-77e491642087' User entered 'None (0)'	System	23 Aug 2020 03:40:36
	System	23 Aug 2020 03:40:36

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:27', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'd0bb7e21-436f-4789-820a-77e491642087' User entered 'None (0)'	System	23 Aug 2020 03:40:36
	System	23 Aug 2020 03:40:36

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:31', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'd0bb7e21-436f-4789-820a-77e491642087'	System	23 Aug 2020 03:40:36
User entered 'No (N)'	System	23 Aug 2020 03:40:36

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-22T22:40:35', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'd0bb7e21-436f-4789-820a-77e491642087'	System	23 Aug 2020 03:40:36
User entered '22 Aug 2020 22:40'	System	23 Aug 2020 03:40:36

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 5'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:46', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9cbce411-f3f6-49f4-8214-fcafe2ab1de5'	System	24 Aug 2020 13:33:16
User entered 'None (0)'	System	24 Aug 2020 13:33:16

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:49', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9cbce411-f3f6-49f4-8214-fcafe2ab1de5'	System	24 Aug 2020 13:33:16
User entered 'None (0)'	System	24 Aug 2020 13:33:16

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:53', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9cbce411-f3f6-49f4-8214-fcafe2ab1de5'	System	24 Aug 2020 13:33:16
User entered 'None (0)'	System	24 Aug 2020 13:33:16

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:32:58', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9cbce411-f3f6-49f4-8214-fcafe2ab1de5'	System	24 Aug 2020 13:33:16
User entered 'None (0)'	System	24 Aug 2020 13:33:16

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:33:03', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9cbce411-f3f6-49f4-8214-fcafe2ab1de5'	System	24 Aug 2020 13:33:16
User entered 'None (0)'	System	24 Aug 2020 13:33:16

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:33:05', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9cbce411-f3f6-49f4-8214-fcafe2ab1de5'	System	24 Aug 2020 13:33:16
User entered 'None (0)'	System	24 Aug 2020 13:33:16

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:33:11', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9cbce411-f3f6-49f4-8214-fcafe2ab1de5'	System	24 Aug 2020 13:33:16
User entered 'No (N)'	System	24 Aug 2020 13:33:16

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-24T08:33:15', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9cbce411-f3f6-49f4-8214-fcafe2ab1de5'	System	24 Aug 2020 13:33:16
User entered '24 Aug 2020 08:33'	System	24 Aug 2020 13:33:16

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 6'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:12', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5432d250-c067-4abe-ab1a-25aab34d1afe' User entered 'None (0)'	System	25 Aug 2020 14:36:42
	System	25 Aug 2020 14:36:42

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:15', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5432d250-c067-4abe-ab1a-25aab34d1afe' User entered 'None (0)'	System	25 Aug 2020 14:36:42
	System	25 Aug 2020 14:36:42

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:17', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5432d250-c067-4abe-ab1a-25aab34d1afe' User entered 'None (0)'	System	25 Aug 2020 14:36:42
	System	25 Aug 2020 14:36:42

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:19', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5432d250-c067-4abe-ab1a-25aab34d1afe' User entered 'None (0)'	System	25 Aug 2020 14:36:42
	System	25 Aug 2020 14:36:42

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:21', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5432d250-c067-4abe-ab1a-25aab34d1afe' User entered 'None (0)'	System	25 Aug 2020 14:36:42
	System	25 Aug 2020 14:36:42

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:23', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5432d250-c067-4abe-ab1a-25aab34d1afe' User entered 'None (0)'	System	25 Aug 2020 14:36:42
	System	25 Aug 2020 14:36:42

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:36', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5432d250-c067-4abe-ab1a-25aab34d1afe' User entered 'Yes (Y)'	System	25 Aug 2020 14:36:42
	System	25 Aug 2020 14:36:42

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-08-25T09:36:39', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5432d250-c067-4abe-ab1a-25aab34d1afe' User entered '25 Aug 2020 09:36'	System	25 Aug 2020 14:36:42
	System	25 Aug 2020 14:36:42

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 7'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:43:09

US3752162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4)	22 Oct 2020 20:07:44
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '27 Aug 2020'	(b) (4)	
	Amanda Horn (b) (4)	22 Oct 2020 20:07:44
	(b) (4)	

US3752162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	22 Oct 2020 20:07:44

US3752162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	22 Oct 2020 20:07:44
	(b) (4)	

US3752162

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	16 Sep 2020 16:09:58

US3752162

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '1'	System	16 Sep 2020 16:09:58

US3752162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4)	22 Sep 2020 19:32:17
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '3 Sep 2020'	(b) (4)	22 Sep 2020 19:32:17
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:32:17

US3752162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	22 Sep 2020 19:32:17
	(b) (4)	

US3752162

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	16 Sep 2020 16:10:15

US3752162

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '1'	System	16 Sep 2020 16:10:15

US3752162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4)	22 Sep 2020 19:32:37
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '10 Sep 2020'	(b) (4)	
	Amanda Horn (b) (4)	22 Sep 2020 19:32:37
	(b) (4)	

US3752162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:32:37

US3752162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	22 Sep 2020 19:32:37
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	16 Sep 2020 16:10:27

US3752162

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'I'	System	16 Sep 2020 16:10:27

US3752162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:17:54

US3752162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:17:54

US3752162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:17:54

US3752162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'VISIT2'	System	17 Sep 2020 16:17:54

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '10:36'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '16 Sep 2020 10:36'	System	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 16:19:46
Query 'Data is required. Please provide.' answered by System	System	17 Sep 2020 16:19:46
data change (Site from System).		
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:19:46
User opened query 'Data is required. Please provide.' (Site from System).		17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 16:19:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 16:19:46
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:19:46
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'bpm'	System	17 Sep 2020 16:19:46
User entered empty.	System	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 16:19:46
Query 'Data is required. Please provide.' answered by System	System	17 Sep 2020 16:19:46
data change (Site from System).		17 Sep 2020 16:19:46
User entered '12' reason for change: Data Entry	(b) (4), (b) (6)	17 Sep 2020 16:19:46
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'breaths/min'	System	17 Sep 2020 16:19:46
User entered empty.	System	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 16:19:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 16:19:46
User entered '134' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:19:46
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'mmHg'	System	17 Sep 2020 16:19:46
User entered empty.	System	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 16:19:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 16:19:46
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:19:46
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'mmHg'	System	17 Sep 2020 16:19:46
User entered empty.	System	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per CDM: The treatment time on the Exposure CRF is 11:06 and the Vital Signs Post Dose Time of Assessment is 11:25 which has 19 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:11:51
Query 'Per CDM: The treatment time on the Exposure CRF is 11:06 and the Vital Signs Post Dose Time of Assessment is 11:25 which has 19 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' answered with 'SITE INADVERTENTLY TOOK VITALS TOO SOON' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:29:13
User opened query 'Per CDM: The treatment time on the Exposure CRF is 11:06 and the Vital Signs Post Dose Time of Assessment is 11:25 which has 19 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:42:08
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:20:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Sep 2020 16:20:26
User entered '11:25' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:20:26
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '16 Sep 2020 11:25'	System	17 Sep 2020 16:20:26
User entered empty.	System	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 16:20:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 16:20:26
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:20:26
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:20:26
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 16:20:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 16:20:26
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:20:26
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'bpm'	System	17 Sep 2020 16:20:26
User entered empty.	System	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 16:20:26
Query 'Data is required. Please provide.' answered by System	System	17 Sep 2020 16:20:26
data change (Site from System).		
User entered '15' reason for change: Data Entry	(b) (4), (b) (6)	17 Sep 2020 16:20:26
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'breaths/min'	System	17 Sep 2020 16:20:26
User entered empty.	System	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 16:20:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 16:20:26
User entered '130' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:20:26
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'mmHg'	System	17 Sep 2020 16:20:26
User entered empty.	System	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 16:20:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 16:20:26
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:20:26
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 16:19:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'mmHg'	System	17 Sep 2020 16:20:26
User entered empty.	System	17 Sep 2020 16:19:25

US3752162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:20:36

US3752162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:20:36

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	16 Sep 2020 16:10:49

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	16 Sep 2020 16:10:49

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) Lauren Evans (b) (4)	16 Sep 2020 16:10:49

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 16:10:49

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '16 Sep 2020'	(b) (4)	
	Lauren Evans (b) (4)	16 Sep 2020 16:10:49

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '11:06'	(b) (4)	
	Lauren Evans (b) (4)	16 Sep 2020 16:10:49

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '16 Sep 2020 11:06'	System	16 Sep 2020 16:10:49

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Left Arm (LEFT ARM)'	Lauren Evans (b) (4)	16 Sep 2020 16:10:49

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'ONCE'	System	16 Sep 2020 16:10:49

US3752162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 16:10:49

US3752162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:21:02

US3752162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:21:02

US3752162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '10:36'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:21:02

US3752162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '16 Sep 2020 10:36'	System	17 Sep 2020 16:21:02

US3752162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:21:14

US3752162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:26:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Sep 2020 16:21:14

US3752162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:21:14

US3752162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:26:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '10:34'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:21:14

US3752162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:26:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '16 Sep 2020 10:34'	System	17 Sep 2020 16:21:14

US3752162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:26:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Sep 2020 16:21:14

US3752162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:21:14

US3752162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:26:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:21:14

US3752162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:26:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered empty.	System	17 Sep 2020 16:21:14

US3752162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:21:19

US3752162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '1'	System	17 Sep 2020 16:21:19

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:39:43', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '28a9d9fe-9d7f-47a4-a2cd-8f3335d627f7'	System	16 Sep 2020 16:40:09
User entered 'Yes (Y)'	System	16 Sep 2020 16:40:09

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:39:49', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '28a9d9fe-9d7f-47a4-a2cd-8f3335d627f7' User entered '98.8'	System	16 Sep 2020 16:40:09
	System	16 Sep 2020 16:40:09

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:39:54', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '28a9d9fe-9d7f-47a4-a2cd-8f3335d627f7'	System	16 Sep 2020 16:40:09
User entered 'No (N)'	System	16 Sep 2020 16:40:09

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:40:07', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '28a9d9fe-9d7f-47a4-a2cd-8f3335d627f7'	System	16 Sep 2020 16:40:09
User entered '16 Sep 2020 11:40'	System	16 Sep 2020 16:40:09

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '16 Sep 2020 11:26'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '16 Sep 2020 13:56'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:52:12', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f8eeeee9-c9a8-459a-8db5-321c7b348f96'	System	17 Sep 2020 14:54:14
User entered 'Yes (Y)'	System	17 Sep 2020 14:54:14

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:52:17', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f8eeeee9-c9a8-459a-8db5-321c7b348f96' User entered '98.1'	System	17 Sep 2020 14:54:14
	System	17 Sep 2020 14:54:14

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:52:37', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f8eeeee9-c9a8-459a-8db5-321c7b348f96'	System	17 Sep 2020 14:54:14
User entered 'Yes (Y)'	System	17 Sep 2020 14:54:14

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
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 'Site confirmed with subject, EDC being updated accordingly.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 12:33:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 15:07:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:52:44', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f8eeeee9-c9a8-459a-8db5-321c7b348f96'	System	17 Sep 2020 14:54:14
User entered '1'	System	17 Sep 2020 14:54:14

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:52:44', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f8eeeee9-c9a8-459a-8db5-321c7b348f96'	System	17 Sep 2020 14:54:14
User entered '0'	System	17 Sep 2020 14:54:14

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:54:12', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'f8eeeee9-c9a8-459a-8db5-321c7b348f96' User entered '17 Sep 2020 09:54'	System	17 Sep 2020 14:54:14
	System	17 Sep 2020 14:54:14

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '16 Sep 2020 14:51'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 2'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:39:12', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8360972f-8203-4542-92c2-600baeebef47'	System	18 Sep 2020 14:40:12
User entered 'Yes (Y)'	System	18 Sep 2020 14:40:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:39:18', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8360972f-8203-4542-92c2-600baeebef47' User entered '98.1'	System	18 Sep 2020 14:40:12
	System	18 Sep 2020 14:40:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:39:24', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8360972f-8203-4542-92c2-600baeebef47'	System	18 Sep 2020 14:40:12
User entered 'Yes (Y)'	System	18 Sep 2020 14:40:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
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 'Site confirmed with subject, EDC being updated accordingly.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 12:33:38
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).	(b) (4), (b) (6)	23 Sep 2020 15:08:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:05', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8360972f-8203-4542-92c2-600baeebef47'	System	18 Sep 2020 14:40:12
User entered '1'	System	18 Sep 2020 14:40:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:05', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8360972f-8203-4542-92c2-600baeebef47'	System	18 Sep 2020 14:40:12
User entered '0'	System	18 Sep 2020 14:40:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:09', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8360972f-8203-4542-92c2-600baeebef47'	System	18 Sep 2020 14:40:12
User entered '18 Sep 2020 09:40'	System	18 Sep 2020 14:40:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 3'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 4'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T09:49:34', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '10aa1caf-a793-4588-846f-42631db65a35'	System	20 Sep 2020 14:50:30
User entered 'Yes (Y)'	System	20 Sep 2020 14:50:30

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T09:49:50', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '10aa1caf-a793-4588-846f-42631db65a35' User entered '97.8'	System	20 Sep 2020 14:50:30
	System	20 Sep 2020 14:50:30

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T09:50:08', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '10aa1caf-a793-4588-846f-42631db65a35'	System	20 Sep 2020 14:50:30
User entered 'Yes (Y)'	System	20 Sep 2020 14:50:30

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
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 'Site confirmed with subject, EDC being updated accordingly.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 12:33:43
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).	(b) (4), (b) (6)	23 Sep 2020 15:08:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T09:50:17', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '10aa1caf-a793-4588-846f-42631db65a35'	System	20 Sep 2020 14:50:30
User entered '1'	System	20 Sep 2020 14:50:30

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T09:50:17', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '10aa1caf-a793-4588-846f-42631db65a35' User entered '0'	System	20 Sep 2020 14:50:30
	System	20 Sep 2020 14:50:30

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T09:50:26', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '10aa1caf-a793-4588-846f-42631db65a35'	System	20 Sep 2020 14:50:30
User entered '20 Sep 2020 09:50'	System	20 Sep 2020 14:50:30

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 5'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 6'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:58:39', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '033e4201-724f-4203-9bcc-5c4daf310853' User entered 'Yes (Y)'	System	21 Sep 2020 20:59:01
	System	21 Sep 2020 20:59:01

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:58:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '033e4201-724f-4203-9bcc-5c4daf310853' User entered '97.5'	System	21 Sep 2020 20:59:01
	System	21 Sep 2020 20:59:01

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:58:54', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '033e4201-724f-4203-9bcc-5c4daf310853'	System	21 Sep 2020 20:59:01
User entered 'No (N)'	System	21 Sep 2020 20:59:01

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:58:59', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '033e4201-724f-4203-9bcc-5c4daf310853' User entered '21 Sep 2020 15:58'	System	21 Sep 2020 20:59:01
	System	21 Sep 2020 20:59:01

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 7'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:40:28', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'a332703d-ce03-4a50-a1e5-3f2570b6d12e'	System	16 Sep 2020 16:41:19
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 16:41:19

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:40:31', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'a332703d-ce03-4a50-a1e5-3f2570b6d12e' User entered 'No (N)'	System	16 Sep 2020 16:41:19
	System	16 Sep 2020 16:41:19

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:40:40', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'a332703d-ce03-4a50-a1e5-3f2570b6d12e' User entered 'No (N)'	System	16 Sep 2020 16:41:19
	System	16 Sep 2020 16:41:19

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:40:45', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'a332703d-ce03-4a50-a1e5-3f2570b6d12e' User entered 'None (1)'	System	16 Sep 2020 16:41:19
	System	16 Sep 2020 16:41:19

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:40:50', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'a332703d-ce03-4a50-a1e5-3f2570b6d12e' User entered '16 Sep 2020 11:40'	System	16 Sep 2020 16:41:19
	System	16 Sep 2020 16:41:19

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '16 Sep 2020 11:26'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '16 Sep 2020 13:56'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:54:35', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5117a466-64fa-4539-80e8-9356276a6aa9'	System	17 Sep 2020 14:54:57
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 14:54:57

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:54:40', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5117a466-64fa-4539-80e8-9356276a6aa9' User entered 'No (N)'	System	17 Sep 2020 14:54:57
	System	17 Sep 2020 14:54:57

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:54:45', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5117a466-64fa-4539-80e8-9356276a6aa9' User entered 'No (N)'	System	17 Sep 2020 14:54:57
	System	17 Sep 2020 14:54:57

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:54:49', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5117a466-64fa-4539-80e8-9356276a6aa9' User entered 'None (1)'	System	17 Sep 2020 14:54:57
	System	17 Sep 2020 14:54:57

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:54:53', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '5117a466-64fa-4539-80e8-9356276a6aa9' User entered '17 Sep 2020 09:54'	System	17 Sep 2020 14:54:57
	System	17 Sep 2020 14:54:57

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '16 Sep 2020 14:51'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 2'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:56', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '65244ebe-8321-412a-825a-45b1ae7ccf30'	System	18 Sep 2020 14:41:17
User entered 'None (1)'	System	18 Sep 2020 14:41:17

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:59', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '65244ebe-8321-412a-825a-45b1ae7ccf30'	System	18 Sep 2020 14:41:17
User entered 'No (N)'	System	18 Sep 2020 14:41:17

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:41:04', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '65244ebe-8321-412a-825a-45b1ae7ccf30'	System	18 Sep 2020 14:41:17
User entered 'No (N)'	System	18 Sep 2020 14:41:17

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:41:08', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '65244ebe-8321-412a-825a-45b1ae7ccf30'	System	18 Sep 2020 14:41:17
User entered 'None (1)'	System	18 Sep 2020 14:41:17

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:41:15', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '65244ebe-8321-412a-825a-45b1ae7ccf30' User entered '18 Sep 2020 09:41'	System	18 Sep 2020 14:41:17
	System	18 Sep 2020 14:41:17

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 3'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 4'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:04', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'fc736943-9a21-49da-9e55-e6820b3320d8'	System	20 Sep 2020 14:49:26
User entered 'None (1)'	System	20 Sep 2020 14:49:26

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:07', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'fc736943-9a21-49da-9e55-e6820b3320d8'	System	20 Sep 2020 14:49:26
User entered 'No (N)'	System	20 Sep 2020 14:49:26

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:10', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'fc736943-9a21-49da-9e55-e6820b3320d8' User entered 'No (N)'	System	20 Sep 2020 14:49:26
	System	20 Sep 2020 14:49:26

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:14', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'fc736943-9a21-49da-9e55-e6820b3320d8'	System	20 Sep 2020 14:49:26
User entered 'None (1)'	System	20 Sep 2020 14:49:26

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:18', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'fc736943-9a21-49da-9e55-e6820b3320d8' User entered '20 Sep 2020 08:53'	System	20 Sep 2020 14:49:26
	System	20 Sep 2020 14:49:26

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 5'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 6'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:03', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '262065e1-2e53-4c9f-9320-57aa58a36691' User entered 'None (1)'	System	21 Sep 2020 20:59:24
	System	21 Sep 2020 20:59:24

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:07', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '262065e1-2e53-4c9f-9320-57aa58a36691' User entered 'No (N)'	System	21 Sep 2020 20:59:24
	System	21 Sep 2020 20:59:24

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:10', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '262065e1-2e53-4c9f-9320-57aa58a36691' User entered 'No (N)'	System	21 Sep 2020 20:59:24
	System	21 Sep 2020 20:59:24

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:13', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '262065e1-2e53-4c9f-9320-57aa58a36691' User entered 'None (1)'	System	21 Sep 2020 20:59:24
	System	21 Sep 2020 20:59:24

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:16', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '262065e1-2e53-4c9f-9320-57aa58a36691' User entered '21 Sep 2020 15:59'	System	21 Sep 2020 20:59:24
	System	21 Sep 2020 20:59:24

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 7'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:40:57', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '295521dc-e25a-409c-a484-a569a954e4d2' User entered 'None (0)'	System	16 Sep 2020 16:41:48
	System	16 Sep 2020 16:41:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:41:07', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '295521dc-e25a-409c-a484-a569a954e4d2' User entered 'None (0)'	System	16 Sep 2020 16:41:48
	System	16 Sep 2020 16:41:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:41:11', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '295521dc-e25a-409c-a484-a569a954e4d2' User entered 'None (0)'	System	16 Sep 2020 16:41:48
	System	16 Sep 2020 16:41:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:41:14', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '295521dc-e25a-409c-a484-a569a954e4d2' User entered 'None (0)'	System	16 Sep 2020 16:41:48
	System	16 Sep 2020 16:41:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:41:17', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '295521dc-e25a-409c-a484-a569a954e4d2' User entered 'None (0)'	System	16 Sep 2020 16:41:48
	System	16 Sep 2020 16:41:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:41:20', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '295521dc-e25a-409c-a484-a569a954e4d2' User entered 'None (0)'	System	16 Sep 2020 16:41:48
	System	16 Sep 2020 16:41:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:41:43', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '295521dc-e25a-409c-a484-a569a954e4d2' User entered 'No (N)'	System	16 Sep 2020 16:41:48
	System	16 Sep 2020 16:41:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-16T11:41:46', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '295521dc-e25a-409c-a484-a569a954e4d2'	System	16 Sep 2020 16:41:48
User entered '16 Sep 2020 11:41'	System	16 Sep 2020 16:41:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '16 Sep 2020 11:26'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '16 Sep 2020 13:56'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:55:03', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2645a82b-0e2f-4fd5-af93-bc59cd60ef88' User entered 'None (0)'	System	17 Sep 2020 14:56:11
	System	17 Sep 2020 14:56:11

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:55:05', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2645a82b-0e2f-4fd5-af93-bc59cd60ef88' User entered 'None (0)'	System	17 Sep 2020 14:56:11
	System	17 Sep 2020 14:56:11

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:55:35', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2645a82b-0e2f-4fd5-af93-bc59cd60ef88'	System	17 Sep 2020 14:56:11
User entered 'Some interference with activity (2)'	System	17 Sep 2020 14:56:11

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:55:43', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2645a82b-0e2f-4fd5-af93-bc59cd60ef88' User entered 'None (0)'	System	17 Sep 2020 14:56:11
	System	17 Sep 2020 14:56:11

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:55:49', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2645a82b-0e2f-4fd5-af93-bc59cd60ef88' User entered 'None (0)'	System	17 Sep 2020 14:56:11
	System	17 Sep 2020 14:56:11

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:55:53', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2645a82b-0e2f-4fd5-af93-bc59cd60ef88' User entered 'None (0)'	System	17 Sep 2020 14:56:11
	System	17 Sep 2020 14:56:11

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:56:04', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2645a82b-0e2f-4fd5-af93-bc59cd60ef88'	System	17 Sep 2020 14:56:11
User entered 'Yes (Y)'	System	17 Sep 2020 14:56:11

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-17T09:56:08', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2645a82b-0e2f-4fd5-af93-bc59cd60ef88'	System	17 Sep 2020 14:56:11
User entered '17 Sep 2020 09:56'	System	17 Sep 2020 14:56:11

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '16 Sep 2020 14:51'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 2'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:17', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '329572d1-0fbf-486e-a547-690c4a808a30' User entered 'None (0)'	System	18 Sep 2020 14:40:48
	System	18 Sep 2020 14:40:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:20', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '329572d1-0fbf-486e-a547-690c4a808a30' User entered 'None (0)'	System	18 Sep 2020 14:40:48
	System	18 Sep 2020 14:40:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:25', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '329572d1-0fbf-486e-a547-690c4a808a30' User entered 'None (0)'	System	18 Sep 2020 14:40:48
	System	18 Sep 2020 14:40:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:28', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '329572d1-0fbf-486e-a547-690c4a808a30' User entered 'None (0)'	System	18 Sep 2020 14:40:48
	System	18 Sep 2020 14:40:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:31', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '329572d1-0fbf-486e-a547-690c4a808a30' User entered 'None (0)'	System	18 Sep 2020 14:40:48
	System	18 Sep 2020 14:40:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:33', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '329572d1-0fbf-486e-a547-690c4a808a30' User entered 'None (0)'	System	18 Sep 2020 14:40:48
	System	18 Sep 2020 14:40:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:41', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '329572d1-0fbf-486e-a547-690c4a808a30' User entered 'Yes (Y)'	System	18 Sep 2020 14:40:48
	System	18 Sep 2020 14:40:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-18T09:40:45', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '329572d1-0fbf-486e-a547-690c4a808a30' User entered '18 Sep 2020 09:40'	System	18 Sep 2020 14:40:48
	System	18 Sep 2020 14:40:48

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 3'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 4'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:26', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'efc4a768-ffad-4469-8f7e-1a9ec8e4a09f' User entered 'None (0)'	System	20 Sep 2020 14:49:27
	System	20 Sep 2020 14:49:27

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:29', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'efc4a768-ffad-4469-8f7e-1a9ec8e4a09f' User entered 'None (0)'	System	20 Sep 2020 14:49:27
	System	20 Sep 2020 14:49:27

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:33', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'efc4a768-ffad-4469-8f7e-1a9ec8e4a09f' User entered 'None (0)'	System	20 Sep 2020 14:49:27
	System	20 Sep 2020 14:49:27

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:35', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'efc4a768-ffad-4469-8f7e-1a9ec8e4a09f' User entered 'None (0)'	System	20 Sep 2020 14:49:27
	System	20 Sep 2020 14:49:27

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:38', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'efc4a768-ffad-4469-8f7e-1a9ec8e4a09f' User entered 'None (0)'	System	20 Sep 2020 14:49:27
	System	20 Sep 2020 14:49:27

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:40', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'efc4a768-ffad-4469-8f7e-1a9ec8e4a09f' User entered 'None (0)'	System	20 Sep 2020 14:49:27
	System	20 Sep 2020 14:49:27

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:54', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'efc4a768-ffad-4469-8f7e-1a9ec8e4a09f' User entered 'No (N)'	System	20 Sep 2020 14:49:27
	System	20 Sep 2020 14:49:27

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-20T08:53:58', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'efc4a768-ffad-4469-8f7e-1a9ec8e4a09f' User entered '20 Sep 2020 08:53'	System	20 Sep 2020 14:49:27
	System	20 Sep 2020 14:49:27

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 5'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 6'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:22', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2c039a45-9dbf-473b-aa06-9421c04e6b8e' User entered 'None (0)'	System	21 Sep 2020 20:59:46
	System	21 Sep 2020 20:59:46

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:24', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2c039a45-9dbf-473b-aa06-9421c04e6b8e' User entered 'None (0)'	System	21 Sep 2020 20:59:46
	System	21 Sep 2020 20:59:46

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:26', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2c039a45-9dbf-473b-aa06-9421c04e6b8e' User entered 'None (0)'	System	21 Sep 2020 20:59:46
	System	21 Sep 2020 20:59:46

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:29', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2c039a45-9dbf-473b-aa06-9421c04e6b8e' User entered 'None (0)'	System	21 Sep 2020 20:59:46
	System	21 Sep 2020 20:59:46

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:32', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2c039a45-9dbf-473b-aa06-9421c04e6b8e' User entered 'None (0)'	System	21 Sep 2020 20:59:46
	System	21 Sep 2020 20:59:46

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:34', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2c039a45-9dbf-473b-aa06-9421c04e6b8e' User entered 'None (0)'	System	21 Sep 2020 20:59:46
	System	21 Sep 2020 20:59:46

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:40', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2c039a45-9dbf-473b-aa06-9421c04e6b8e' User entered 'Yes (Y)'	System	21 Sep 2020 20:59:46
	System	21 Sep 2020 20:59:46

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-09-21T15:59:43', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '2c039a45-9dbf-473b-aa06-9421c04e6b8e' User entered '21 Sep 2020 15:59'	System	21 Sep 2020 20:59:46
	System	21 Sep 2020 20:59:46

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
Data entry locked.	System	16 Sep 2020 16:10:49
User entered 'Day 7'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

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 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 16:10:49

US3752162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:12
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 16:10:49

US3752162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:44:44

US3752162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:44:44

US3752162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:44:44

US3752162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:44:44

US3752162

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:33:25

US3752162

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '1'	System	08 Oct 2020 14:33:25

US3752162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4)	30 Oct 2020 19:11:08
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '30 Sep 2020'	(b) (4)	
	Amanda Horn (b) (4)	30 Oct 2020 19:11:08
	(b) (4)	

US3752162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:11:08

US3752162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	30 Oct 2020 19:11:08
	(b) (4)	

US3752162

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:33:36

US3752162

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'I'	System	08 Oct 2020 14:33:36

US3752162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4)	30 Oct 2020 19:11:23
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '7 Oct 2020'	(b) (4)	
	Amanda Horn (b) (4)	30 Oct 2020 19:11:23
	(b) (4)	

US3752162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:11:23

US3752162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	30 Oct 2020 19:11:23
	(b) (4)	

US3752162

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
Query 'Per GCL Lab Recon: Saliva: Sample dated 27OCT2020 for COVID PCR Saliva is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 04:33:52
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 27OCT2020 for COVID PCR Saliva is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:39:55
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:11:27

US3752162

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'I'	System	30 Oct 2020 19:11:27

US3752162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:18:31
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	10 Mar 2021 18:31:18

US3752162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:18:31
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	10 Mar 2021 18:31:18

US3752162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:18:31
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	10 Mar 2021 18:31:18

US3752162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'VISIT3'	System	10 Mar 2021 18:31:18

US3752162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 21:30:35
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered '1'	System	23 Feb 2021 21:30:35

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 64'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Have you been exposed to someone with 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 71'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Have you been exposed to someone with 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 78'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Have you been exposed to someone with 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3752162

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered 'Day 92'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Have you been exposed to someone with 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 20:43:09

US3752162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:16:38
Data entry locked.	System	19 Aug 2020 20:43:09
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 20:43:09

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered 'Yes (Y)'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:12', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered 'No (N)'	System	08 Dec 2020 17:30:32
	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:18', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered 'Yes (Y)'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '1'	System	08 Dec 2020 17:30:32
	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '0'	System	08 Dec 2020 17:30:32
	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '0'	System	08 Dec 2020 17:30:32
	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:48', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered '1'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:29:55', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:30:03', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered 'Yes (Y)'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Please 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:30:07', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0'	System	08 Dec 2020 17:30:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-08T11:30:18', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'e92915a2-ce1c-48c7-890f-5d6596a019d0' User entered '08 Dec 2020 11:30:18'	System	08 Dec 2020 17:30:32
	System	08 Dec 2020 17:30:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-22T08:35:07', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8cc042da-f528-47bf-99e4-fc73343c98d2'	System	22 Dec 2020 14:35:28
User entered 'No (N)'	System	22 Dec 2020 14:35:28

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-22T08:35:15', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8cc042da-f528-47bf-99e4-fc73343c98d2'	System	22 Dec 2020 14:35:28
User entered 'No (N)'	System	22 Dec 2020 14:35:28

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-22T08:35:25', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8cc042da-f528-47bf-99e4-fc73343c98d2' User entered '22 Dec 2020 08:35:25'	System	22 Dec 2020 14:35:28
	System	22 Dec 2020 14:35:28

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-29T12:00:54', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8d540546-38f3-46d1-a40d-7dd6c9be0b4e' User entered 'No (N)'	System	29 Dec 2020 18:01:38
	System	29 Dec 2020 18:01:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-29T12:01:25', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8d540546-38f3-46d1-a40d-7dd6c9be0b4e'	System	29 Dec 2020 18:01:38
User entered 'No (N)'	System	29 Dec 2020 18:01:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2020-12-29T12:01:36', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '8d540546-38f3-46d1-a40d-7dd6c9be0b4e' User entered '29 Dec 2020 12:01:36'	System	29 Dec 2020 18:01:38
	System	29 Dec 2020 18:01:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-01-18T17:44:26', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'ff818110-5971-4109-84e1-9d3eb258b997'	System	18 Jan 2021 23:44:43
User entered 'No (N)'	System	18 Jan 2021 23:44:43

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-01-18T17:44:35', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'ff818110-5971-4109-84e1-9d3eb258b997'	System	18 Jan 2021 23:44:43
User entered 'No (N)'	System	18 Jan 2021 23:44:43

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-01-18T17:44:40', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'ff818110-5971-4109-84e1-9d3eb258b997' User entered '18 Jan 2021 17:44:40'	System	18 Jan 2021 23:44:43
	System	18 Jan 2021 23:44:43

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-02-01T18:00:53', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9d671809-3453-452b-96e4-af11aa60eb0c' User entered 'No (N)'	System	02 Feb 2021 00:02:20
	System	02 Feb 2021 00:02:20

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-02-01T18:00:59', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9d671809-3453-452b-96e4-af11aa60eb0c' User entered 'No (N)'	System	02 Feb 2021 00:02:20
	System	02 Feb 2021 00:02:20

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-02-01T18:01:06', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '9d671809-3453-452b-96e4-af11aa60eb0c' User entered '01 Feb 2021 18:01:06'	System	02 Feb 2021 00:02:20
	System	02 Feb 2021 00:02:20

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-02-15T18:37:12', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'a3b670b3-3835-4b79-b6cc-e7c5b7bb43a0' User entered 'No (N)'	System	16 Feb 2021 00:37:38
	System	16 Feb 2021 00:37:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-02-15T18:37:23', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'a3b670b3-3835-4b79-b6cc-e7c5b7bb43a0' User entered 'No (N)'	System	16 Feb 2021 00:37:38
	System	16 Feb 2021 00:37:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-02-15T18:37:34', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'a3b670b3-3835-4b79-b6cc-e7c5b7bb43a0' User entered '15 Feb 2021 18:37:34'	System	16 Feb 2021 00:37:38
	System	16 Feb 2021 00:37:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-09T17:32:09-06:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '20120ad5-8087-4886-8827-8f2a2d7f78de' User entered 'No (N)'	System	09 Mar 2021 23:33:08
	System	09 Mar 2021 23:33:08

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-09T17:32:17-06:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '20120ad5-8087-4886-8827-8f2a2d7f78de'	System	09 Mar 2021 23:33:08
User entered 'No (N)'	System	09 Mar 2021 23:33:08

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-09T17:32:26-06:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '20120ad5-8087-4886-8827-8f2a2d7f78de'	System	09 Mar 2021 23:33:08
User entered '09 Mar 2021 17:32:26'	System	09 Mar 2021 23:33:08

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-16T12:53:55-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'b0ec36de-d948-401d-a443-13dc2e88e4c0'	System	16 Mar 2021 17:55:27
User entered 'No (N)'	System	16 Mar 2021 17:55:27

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-16T12:54:00-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'b0ec36de-d948-401d-a443-13dc2e88e4c0'	System	16 Mar 2021 17:55:27
User entered 'No (N)'	System	16 Mar 2021 17:55:27

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-16T12:55:24-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'b0ec36de-d948-401d-a443-13dc2e88e4c0' User entered '16 Mar 2021 12:55:24'	System	16 Mar 2021 17:55:27
	System	16 Mar 2021 17:55:27

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-21T12:00:46-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '52fb73d7-9c6c-4a42-a0bc-c812793ebc79'	System	21 Mar 2021 17:01:32
User entered 'No (N)'	System	21 Mar 2021 17:01:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-21T12:00:50-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '52fb73d7-9c6c-4a42-a0bc-c812793ebc79'	System	21 Mar 2021 17:01:32
User entered 'No (N)'	System	21 Mar 2021 17:01:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-21T12:01:00-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '52fb73d7-9c6c-4a42-a0bc-c812793ebc79'	System	21 Mar 2021 17:01:32
User entered '21 Mar 2021 12:01:00'	System	21 Mar 2021 17:01:32

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-30T21:26:43-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '0859eabb-4952-4b83-af3e-397fca8585f4'	System	31 Mar 2021 02:26:53
User entered 'No (N)'	System	31 Mar 2021 02:26:53

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-30T21:26:47-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '0859eabb-4952-4b83-af3e-397fca8585f4'	System	31 Mar 2021 02:26:53
User entered 'No (N)'	System	31 Mar 2021 02:26:53

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-30T21:26:51-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '0859eabb-4952-4b83-af3e-397fca8585f4' User entered '30 Mar 2021 21:26:51'	System	31 Mar 2021 02:26:53
	System	31 Mar 2021 02:26:53

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-04-12T18:38:43-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7828c1c3-53c1-4301-94da-fc4808011a9a' User entered 'No (N)'	System	12 Apr 2021 23:39:10
	System	12 Apr 2021 23:39:10

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-04-12T18:38:51-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7828c1c3-53c1-4301-94da-fc4808011a9a' User entered 'No (N)'	System	12 Apr 2021 23:39:10
	System	12 Apr 2021 23:39:10

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-04-12T18:39:03-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '7828c1c3-53c1-4301-94da-fc4808011a9a'	System	12 Apr 2021 23:39:10
User entered '12 Apr 2021 18:39:03'	System	12 Apr 2021 23:39:10

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-04-18T12:01:02-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '425eafd3-b207-496a-bb3b-7e6a5e2aa528'	System	18 Apr 2021 17:03:45
User entered 'No (N)'	System	18 Apr 2021 17:03:45

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-04-18T12:01:09-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '425eafd3-b207-496a-bb3b-7e6a5e2aa528'	System	18 Apr 2021 17:03:45
User entered 'No (N)'	System	18 Apr 2021 17:03:45

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-04-18T12:01:13-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '425eafd3-b207-496a-bb3b-7e6a5e2aa528'	System	18 Apr 2021 17:03:45
User entered '18 Apr 2021 12:01:13'	System	18 Apr 2021 17:03:45

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-04-27T13:04:58-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '950b6230-d87f-45ce-bda7-2b8619529009' User entered 'No (N)'	System	29 Apr 2021 05:39:10
	System	29 Apr 2021 05:39:10

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Have you been exposed to someone with 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 (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-04-27T13:05:04-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '950b6230-d87f-45ce-bda7-2b8619529009' User entered 'No (N)'	System	29 Apr 2021 05:39:10
	System	29 Apr 2021 05:39:10

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-04-27T13:05:12-05:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: '950b6230-d87f-45ce-bda7-2b8619529009'	System	29 Apr 2021 05:39:10
User entered '27 Apr 2021 13:05:12'	System	29 Apr 2021 05:39:10

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:16:38

US3752162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:26:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:16:38
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:16:38

US3752162

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:26:31

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 13:45:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-09T17:32:42-06:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'b809b8ac-5d39-4b2c-bc3c-069d1971b6df'	System	09 Mar 2021 23:33:36
User entered 'No (N)'	System	09 Mar 2021 23:33:36

US3752162

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:26:31

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3017370A-9EE0-4D14-BCC3-8BB54B4575BA)', Time: '2021-03-09T17:32:47-06:00', User OID: 'PatientReportedOutcome (US3752162)', ODM File OID: 'b809b8ac-5d39-4b2c-bc3c-069d1971b6df' User entered '09 Mar 2021 17:32:47'	System	09 Mar 2021 23:33:36
	System	09 Mar 2021 23:33:36

US3752162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 21:35:11
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '12 Nov 2020'	(b) (4)	
	Amanda Horn (b) (4)	23 Feb 2021 21:35:11
	(b) (4)	

US3752162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:35:11

US3752162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	23 Feb 2021 21:35:11
	(b) (4)	

US3752162

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 21:35:17
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:04:33
User entered 'I'	System	23 Feb 2021 21:35:17

US3752162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 21:35:30
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '16 Dec 2020'	(b) (4)	
	Amanda Horn (b) (4)	23 Feb 2021 21:35:30
	(b) (4)	

US3752162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:35:30

US3752162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	23 Feb 2021 21:35:30
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 21:35:33
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered 'I'	System	23 Feb 2021 21:35:33

US3752162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 21:36:31
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '14 Jan 2021'	(b) (4)	
	Amanda Horn (b) (4)	23 Feb 2021 21:36:31
	(b) (4)	

US3752162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:36:31

US3752162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	23 Feb 2021 21:36:31
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 21:36:35
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered 'I'	System	23 Feb 2021 21:36:35

US3752162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 21:38:34
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 14:19:21
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CALL WAS COMPLETED OOW DUE TO INCLEMENT WEATHER, DEVIATION NOTED' (Site from System).	(b) (4)	
	Amanda Horn (b) (4)	23 Feb 2021 21:39:02
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
	System	23 Feb 2021 21:38:34
User entered '17 Feb 2021'	Amanda Horn (b) (4)	23 Feb 2021 21:38:34
	(b) (4)	

US3752162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:38:34

US3752162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	23 Feb 2021 21:38:34
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	23 Feb 2021 21:39:06
	Amanda Horn (b) (4)	
	(b) (4)	

US3752162

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered '1'	System	23 Feb 2021 21:39:06

US3752162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:47:53

US3752162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:47:53

US3752162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:47:53

US3752162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered 'VISIT4'	System	24 Mar 2021 16:47:53

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:16:34
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:16:34
User entered '24 Mar 2021'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:16:34
User entered '11:07'	(b) (4)	
	Lauren Evans (b) (4)	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered '24 Mar 2021 11:07'	System	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:16:34
User entered '98.0' F	(b) (4)	
	Lauren Evans (b) (4)	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:16:34
User entered 'Oral (Oral)'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:16:34
User entered empty.	(b) (4)	30 Mar 2021 20:54:26
	Lauren Evans (b) (4)	

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:16:34
User entered '72'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered 'bpm'	System	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:16:34
User entered '16'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered 'breaths/min'	System	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:16:34
User entered '104'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered 'mmHg'	System	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:16:34
User entered '72'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered 'mmHg'	System	30 Mar 2021 20:54:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38

US3752162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38

US3752162

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:48:05

US3752162

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:48:05

US3752162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:48:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:48:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '11:15'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:48:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered '24 Mar 2021 11:15'	System	24 Mar 2021 16:48:26

US3752162

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:48:31

US3752162

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:15:38
User entered '1'	System	24 Mar 2021 16:48:31

US3752162

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	16 Apr 2021 01:15:46
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	14 Apr 2021 16:48:07
	(b) (4)	

US3752162

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	16 Apr 2021 01:15:46
	(b) (4)	
User entered '14 Apr 2021'	Timothy Campbell (b) (4)	14 Apr 2021 16:48:07
	(b) (4)	

US3752162

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	16 Apr 2021 01:15:46
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Timothy Campbell (b) (4)	14 Apr 2021 16:48:07
	(b) (4)	

US3752162

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	16 Apr 2021 01:15:46
	(b) (4)	
User entered empty.	Timothy Campbell (b) (4)	14 Apr 2021 16:48:07
	(b) (4)	

US3752162

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	16 Apr 2021 01:15:46
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	14 Apr 2021 16:48:12
	(b) (4)	

US3752162

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 16:48:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:26:31

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:28:25
User entered '19 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:26:31

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:28:27
User entered '16:00'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:26:31

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:28
User entered '19 Oct 2020 16:00'	System	30 Oct 2020 15:11:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:26:31

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:28:32
User entered 'Safety Call (Safety Call)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:26:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:28:35
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 1 (Day 1)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:21
User entered '17 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:22
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:25:13
User entered empty.	System	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:26
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:35:32
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:30
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:25:13
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:32
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:25:13
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:10
User closed query 'Per source, fatigue is not reported as a symptom on 17-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:01:08
Query 'Per source, fatigue is not reported as a symptom on 17-Oct-2020. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:04:29
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:04:21
User opened query 'Per source, fatigue is not reported as a symptom on 17-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:36:50
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:03
User closed query 'Per source, Muscle Aches are not reported as a symptom on 17-Oct-2020. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:01:00
Query 'Per source, Muscle Aches are not reported as a symptom on 17-Oct-2020. Please review and reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:04:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:04:21
User opened query 'Per source, Muscle Aches are not reported as a symptom on 17-Oct-2020. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:37:06
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 20:36:53
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:36:51
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:35:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:35:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:34
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:35
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:37
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:25:13
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:38
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:41
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:42
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:44
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:25:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 2 (Day 2)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:48
User entered '18 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:50
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:38:41
User entered '88' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:27:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:27:01
User entered empty.	System	30 Oct 2020 15:11:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:22
User closed query 'Per source, temperature is not recorded on progress notes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:01:19
Query 'Per source, temperature is not recorded on progress notes. Please review and reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:05:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:05:09
User opened query 'Per source, temperature is not recorded on progress notes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:44:17
User entered '100.6' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:27:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:41:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:27:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 17:01:29
User closed query 'Per source, cough was not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:01:27
Query 'Per source, cough was not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:28:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:28:29
User opened query 'Per source, cough was not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:40:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:27:01
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	30 Oct 2020 15:11:21
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:36
User closed query 'Per source, shortness of breath was not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' (Site from CRA). Query 'Per source, shortness of breath was not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:01:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:29:04
User opened query 'Per source, shortness of breath was not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' (Site from CRA). User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:28:29
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:40:36
	Amanda Horn (b) (4)	30 Oct 2020 15:27:01
	(b) (4)	
	Amanda Horn (b) (4)	30 Oct 2020 15:11:21
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:40
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:27:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:57
User entered 'Severe (Severe)' reason for change:	Amanda Horn (b) (4)	30 Oct 2020 15:27:01
Data Entry Error	(b) (4)	
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:49
User closed query 'Per source, muscle aches were not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:01:46
Query 'Per source, muscle aches were not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:29:20
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:28:29
User opened query 'Per source, muscle aches were not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:40:52
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:27:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:54
User closed query 'Per source, body aches were not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:01:51
Query 'Per source, body aches were not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:29:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:28:29
User opened query 'Per source, body aches were not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:41:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:27:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:59
User closed query 'Per source, headache was not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:01:56
Query 'Per source, headache was not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:29:26
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:28:29
User opened query 'Per source, headache was not reported as a symptom on 18-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:41:32
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:27:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:41:52
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:27:01
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:41:50
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:27:01
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:41:49
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:27:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:41:48
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:27:01
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:41:46
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:27:01
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:41:45
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:27:01
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:41:44
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:27:01
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:41:42
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:27:01
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 3 (Day 3)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:05:41
User entered '19 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:05:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:06:36
User closed query 'Per source, O2 Saturation was not reported on 19-Oct-2020. Please provide details on where this data is listed in source. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:02:16
Query 'Per source, O2 Saturation was not reported on 19-Oct-2020. Please provide details on where this data is listed in source. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:30:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:30:16
User opened query 'Per source, O2 Saturation was not reported on 19-Oct-2020. Please provide details on where this data is listed in source. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:48:29
User entered '95' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Form: Symptom Log (3)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:29:58
User entered empty.	System	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:25:07
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 14:51:13
User closed query 'Per CDM: Response noted and thank you for updating O2 Saturation as ND- NOT DONE. Please review and update temperature value as ND - NOT DONE to avoid missing data on this data field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:27:30
Query 'Per CDM: Response noted and thank you for updating O2 Saturation as ND- NOT DONE. Please review and update temperature value as ND - NOT DONE to avoid missing data on this data field. ' answered with 'data updated per query' (Site from DM).	Lauren Evans (b) (4)	20 Apr 2021 13:06:47
DataPoint Un-verified.	Lauren Evans (b) (4)	20 Apr 2021 13:06:08
Signature has been broken.	Lauren Evans (b) (4)	20 Apr 2021 13:06:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Evans (b) (4)	20 Apr 2021 13:06:08
User opened query 'Per CDM: Response noted and thank you for updating O2 Saturation as ND- NOT DONE. Please review and update temperature value as ND - NOT DONE to avoid missing data on this data field. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 07:13:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'per CDM RQ: response noted, please use drop down menu to select not done' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:27:55
Query 'per CDM RQ: response noted, please use drop down menu to select not done' answered with 'it says "not done"' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 16:41:56
User opened query 'per CDM RQ: response noted, please use drop down menu to select not done' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:17:59
User closed query 'Per CDM: it appears that Temperature was not collected for Day 3. If not collected, Please consider recording this as Not Done. Thankyou' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:17:59

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Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

Temperature

Audit	User	Time (GMT)
Query 'Per CDM: it appears that Temperature was not collected for Day 3. If not collected, Please consider recording this as Not Done. Thankyou' answered with 'not done' (Site from DM).	Jamie Pettus (b) (4)	11 Jan 2021 21:10:44
User opened query 'Per CDM: it appears that Temperature was not collected for Day 3. If not collected, Please consider recording this as Not Done. Thankyou' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 14:09:45
User closed query 'Per source, temperature was not reported on 19-Oct-2020. Please provide details on where this data is listed in source. ' (Site from CRA).	(b) (4), (b) (6)	30 Nov 2020 21:06:40
Query 'Per source, temperature was not reported on 19-Oct-2020. Please provide details on where this data is listed in source. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:02:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:30:31
User opened query 'Per source, temperature was not reported on 19-Oct-2020. Please provide details on where this data is listed in source. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:30:16
User entered '098.3' F reason for change: Data Entry Error	(b) (4)	09 Nov 2020 20:48:07
User entered empty.	Amanda Horn (b) (4)	30 Oct 2020 15:29:58
	(b) (4)	
	Amanda Horn (b) (4)	30 Oct 2020 15:11:29
	(b) (4)	

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:09:44
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Form: Symptom Log (3)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:09:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:14
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:16
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Form: Symptom Log (3)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:18
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:19
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:22
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:29:58
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:30
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:31
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:29:58
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:32
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:34
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:37
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:38
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:29:58
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:10:41
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:29:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 4 (Day 4)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:57:36
User entered '20 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:28
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:55
User entered '98' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:33:24
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:33:24
User entered empty.	System	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:02:32
User closed query 'Please remove leading zero. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:02:30
Query 'Please remove leading zero. ' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:30:52
User entered '99.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:30:45
User opened query 'Please remove leading zero. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:57:12
User entered '099.6' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:33:24
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:04
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:57:39
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:51:03
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:57:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:33:24
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:05
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:57:57
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:33:24
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:07
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:10
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:11
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:13
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:15
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:33:24
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:16
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:18
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:19
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:33:24
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:20
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:22
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:23
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:33:24
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:38

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 5 (Day 5)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:58:58
User entered '21 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:01
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:02
User entered '94' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:34:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:34:18
User entered empty.	System	30 Oct 2020 15:11:46

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:02:45
User closed query 'Please remove leading zero. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:02:41
Query 'Please remove leading zero. ' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:31:09
User entered '99.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:31:02
User opened query 'Please remove leading zero. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:59:13
User entered '099.9' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:34:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:55
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:34:18
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:34:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:34:18
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:53
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:34:18
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:26
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:34:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:50
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:34:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:49
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:34:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:47
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:34:18
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:45
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:34:18
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:43
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:34:18
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:42
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:34:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:31
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:34:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:40
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:34:18
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:37
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:34:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:35
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:34:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:59:33
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:34:18
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:46

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 6 (Day 6)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:00:10
User entered '22 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:37
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:00:21
User entered '95' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:35:28
User entered empty.	System	30 Oct 2020 15:11:55

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:01
User closed query 'Please remove leading zero. Per source, temperature is recorded as 99.0 F' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:02:58
Query 'Please remove leading zero. Per source, temperature is recorded as 99.0 F' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:40:08
User entered '99.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:39:59
User opened query 'Please remove leading zero. Per source, temperature is recorded as 99.0 F' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 21:00:55
User entered '099.7' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:34
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:35:28
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:32
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:31
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:35:28
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:06
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:29
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:27
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:35:28
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:26
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:35:28
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:10
User entered 'Severe (Severe)' reason for change:	Amanda Horn (b) (4)	30 Oct 2020 15:35:28
Data Entry Error	(b) (4)	
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:12
User entered 'Severe (Severe)' reason for change:	Amanda Horn (b) (4)	30 Oct 2020 15:35:28
Data Entry Error	(b) (4)	
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:24
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:22
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:21
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:35:28
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:20
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:18
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:35:28
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:11:55

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 7 (Day 7)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:52
User entered '23 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:03
User entered '96' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:35:45
User entered empty.	System	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:01:54
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Oct 2020 15:39:27
User entered '100.0' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Oct 2020 15:35:45
User entered '100' (non-conformant).	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:35:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:53
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:51
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:47
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:39:27
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:44
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:39:27
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:42
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:39:27
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:23
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:36
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:33
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:39:27
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:30
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:29
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:39:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:27
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:39:27
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:02:25
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:39:27
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:03

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 8 (Day 8)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:12
User entered '24 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:23
User entered '98' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:40:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:40:32
User entered empty.	System	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:21
User entered '100.0' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:40:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:40:32
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:40:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:11
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:40:32
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:07
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:40:32
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:38
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:40:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:05
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:40:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:02
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:40:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:00
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:40:32
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:58
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:40:32
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:55
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:40:32
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:53
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:40:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:51
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:40:32
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:48
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:40:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:46
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:40:32
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:40:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:03:44
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:40:32
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:12

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 9 (Day 9)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:24
User entered '25 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:32
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:31
User entered '98' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:41:45
User entered empty.	System	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:28
User entered '100.1' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:40
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:08
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:06
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:41:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:42
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:03
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:01
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:58
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:55
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:41:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:53
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:52
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:41:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:50
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:48
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:47
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:41:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:04:46
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:41:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 10 (Day 10)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:21
User entered '26 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:32
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:34
User entered '95' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:42:46
User entered empty.	System	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:20
User closed query 'Please remove leading zero. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:03:17
Query 'Please remove leading zero. ' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:40:56
User entered '98.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:40:49
User opened query 'Please remove leading zero. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 21:05:29
User entered '098.6' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:08
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:42:46
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:06
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:04
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:42:46
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:44
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:02
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:00
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:59
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:42:46
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:57
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:42:46
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:55
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:42:46
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:54
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:53
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:42:46
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:51
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:50
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:48
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:42:46
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:05:46
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 11 (Day 11)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:14
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:12:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 15:12:53
User entered '27 Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:53
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:12:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:16
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:20
User entered '96' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:54:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:54:45
User entered empty.	System	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:18
User entered '99.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:54:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:59
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:54:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:54:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:57
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:54:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:55
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:54:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:36
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:54:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:54
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:54:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:52
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:54:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:50
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:54:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:49
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:54:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:48
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:54:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:46
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:54:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:45
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:54:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:43
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:54:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:41
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:54:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:40
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:54:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:06:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:54:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:12:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 12 (Day 12)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:05
User entered '28 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:06
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:10
User entered '96' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:55:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:55:35
User entered empty.	System	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:08
User entered '97.6' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:28:32
User entered '097.6' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:55:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:40
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:55:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:55:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:37
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:55:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:36
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:55:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:17
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:55:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:34
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:55:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:33
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:55:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:30
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:55:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:29
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:55:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:28
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:55:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:26
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:55:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:25
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:55:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:23
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:55:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:22
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:55:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:21
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:55:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:19
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:55:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:01

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 13 (Day 13)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:49
User entered '29 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:51
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:55
User entered '98' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	30 Oct 2020 15:56:36
User entered empty.	System	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:53
User entered '98.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:28:45
User entered '098.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:00
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:02
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:56:36
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:03
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:07:59
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:05
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:06
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:08
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:56:36
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:09
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:56:36
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:11
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:56:36
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:56:36
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:14
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:56:36
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:15
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:17
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:18
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:56:36
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:20
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:56:36
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:10

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 14 (Day 14)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:24
User entered '30 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:31
User entered '98' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:33:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	04 Nov 2020 23:33:40
User entered empty.	System	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:29
User entered '97.4' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:33:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:18:54
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:41
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:43
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:45
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:47
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:18:54
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:48
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:18:54
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:50
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:51
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:52
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:54
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:08:58
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:18:54
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:00
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:18:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:01
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:18:54
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:19

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 15 (Day 15)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:07
User entered '31 Oct 2020'	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:08
User entered '0'	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:19:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	05 Nov 2020 00:19:45
User entered empty.	System	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:19:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:28
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:30
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:19:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:32
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:09:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:19:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:33
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:35
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:19:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:36
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:38
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:40
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:41
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:43
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:44
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:46
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:19:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:48
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:19:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:49
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:19:45
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:06

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 16 (Day 16)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:25
User entered '1 Nov 2020'	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:20:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	05 Nov 2020 00:20:30
User entered empty.	System	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:20:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:38
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:40
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:42
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:44
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:20:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:45
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:20:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:49
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:51
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:20:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:52
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:54
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:55
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:57
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:11:58
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:20:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:12:00
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:12:05
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:12:06
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:20:30
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Nov 2020 23:26:16

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Day 17 (Day 17)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:13:47
User entered '2 Nov 2020'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:13:54
User entered '0'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:13:55
User entered missing code ND - Not Done.	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User entered '%'	System	05 Nov 2020 15:42:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:13:57
User entered missing code ND - Not Done.	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:31
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:33
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:34
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:36
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:38
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:39
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:41
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:43
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:44
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:45
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:46
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:48
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:49
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:50
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:52
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:26:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:14:53
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:42:45

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:26:31

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:15:49
User entered '27 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:20:11

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:26:31

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 20:52:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
Query 'Per GCL Lab Recon: SARS-CoV-2 sample: "Did Subject Test Positive For SARS-CoV-2 by RT-PCR?" is "YES", however there is no record of SARS sample collected on date 27 OCT 2020, recorded in EDC under Illness visit folder. Please enter the SARS sample collected on 27 OCT 2020 in Illness visit folder under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form. Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Jan 2021 16:34:52
User opened query 'Per GCL Lab Recon: SARS-CoV-2 sample: "Did Subject Test Positive For SARS-CoV-2 by RT-PCR?" is "YES", however there is no record of SARS sample collected on date 27 OCT 2020, recorded in EDC under Illness visit folder. Please enter the SARS sample collected on 27 OCT 2020 in Illness visit folder under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 16:31:03
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:15:52
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:20:11

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:26:31

[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 20:52:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:15:56
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)	05 Nov 2020 04:21:13
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 'TEST WAS POSITIVE AND COVID-19 HAS BEEN ADDED TO AE FORM.' (Site from System).	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:20:38
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	30 Oct 2020 15:20:11
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:20:11

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:26:31

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 11:09:48
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'This subject was not seen for his Convalescent Day 1 due to having spinal surgery on 15 OCT 2020. An ePIP was submitted in regards to this since he lives (b) (6) away and he was not cleared to drive and his only means of transportation was his wife who is older and at a higher risk. He was contacted via telemedicine visits/safety calls which was recommended in the ePIP. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	12 Mar 2021 20:13:33
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 19:09:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:17:32
User entered '27 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:20:11

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:26:31

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:17:29
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27OCT2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:26:50
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27OCT2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'SUBJECT UNABLE TO COME TO CLINIC FOR VISIT AND HOME HEALTH VISIT NOT POSSIBLE. SITE DID NOT HAVE A COLLECTION KIT FOR SALIVA PCR ONLY SO THE UNSCHEDULED KIT SUPPLIES WERE USED.' (Site from DM).	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 14:18:06
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27OCT2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 08:07:37
User entered 'Saliva Test (Saliva Test)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:20:11

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:26:31

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:17:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:20:11

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:26:31

[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 20:52:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:19:32
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:20:11

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:26:31

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:19:39
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:20:11

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:26:31

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:19:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:20:11

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:26:31

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '1'	System	30 Oct 2020 15:20:11

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:19
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

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 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

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 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered '18 Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:57:37
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered '18 Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:57:37
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered '88' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:57:37
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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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 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:26:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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Folder: Covid-19 Assessment 19 Oct 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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Folder: Covid-19 Assessment 19 Oct 2020

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:31:34
Query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly.' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 20:31:45
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 04:37:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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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 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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Folder: Covid-19 Assessment 19 Oct 2020

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:02:00
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Un-verified.	(b) (4)	01 Mar 2021 20:31:31
Signature has been broken.	Jamie Pettus (b) (4)	01 Mar 2021 20:31:31
User entered empty; reason for change Data Entry Error	(b) (4)	01 Mar 2021 20:31:31
User signature succeeded.	Jamie Pettus (b) (4)	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	09 Nov 2020 21:20:22
User entered 'No (N)'	(b) (4), (b) (6)	
	Amanda Horn (b) (4)	30 Oct 2020 15:23:29
	(b) (4)	

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:02:02
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Un-verified.	(b) (4)	01 Mar 2021 20:31:31
Signature has been broken.	Jamie Pettus (b) (4)	01 Mar 2021 20:31:31
User entered empty; reason for change Data Entry Error	(b) (4)	01 Mar 2021 20:31:31
User signature succeeded.	Jamie Pettus (b) (4)	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	09 Nov 2020 21:20:22
User entered 'No (N)'	(b) (4), (b) (6)	
	Amanda Horn (b) (4)	30 Oct 2020 15:23:29
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:02:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Un-verified.	(b) (4)	01 Mar 2021 20:31:31
Signature has been broken.	Jamie Pettus (b) (4)	01 Mar 2021 20:31:31
User entered empty; reason for change Data Entry Error	(b) (4)	01 Mar 2021 20:31:31
User signature succeeded.	Jamie Pettus (b) (4)	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	09 Nov 2020 21:20:22
User entered 'No (N)'	(b) (4), (b) (6)	
	Amanda Horn (b) (4)	30 Oct 2020 15:23:29
	(b) (4)	

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:02:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Un-verified.	(b) (4)	01 Mar 2021 20:31:31
Signature has been broken.	Jamie Pettus (b) (4)	01 Mar 2021 20:31:31
User entered empty; reason for change Data Entry Error	(b) (4)	01 Mar 2021 20:31:31
User signature succeeded.	Jamie Pettus (b) (4)	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	09 Nov 2020 21:20:22
User entered 'No (N)'	(b) (4), (b) (6)	
	Amanda Horn (b) (4)	30 Oct 2020 15:23:29
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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Folder: Covid-19 Assessment 19 Oct 2020

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Generated On: 12 Aug 2021 13:26:31

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
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[Clinical Evidence](#)

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[Radiographical Evidence](#)

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[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 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:20:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:23:29

US3752162

Folder: Covid-19 Assessment 19 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:26:31

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:02:32
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:18:31
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	10 Mar 2021 18:32:03

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:26:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User accepted default value 'Day 3 (Day 3)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:26:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:30:40
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:30:42
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:26:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User accepted default value 'Day 5 (Day 5)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:26:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:30:46
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:30:47
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:26:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User accepted default value 'Day 7 (Day 7)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:26:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:30:50
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:30:51
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:26:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 27Oct2020 is reported under Illness Visit Day 9 in EDC, however same is reported for Day 28 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:05:03
Query 'Per GCL Lab Recon: Saliva: Sample dated 27Oct2020 is reported under Illness Visit Day 9 in EDC, however same is reported for Day 28 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' answered with 'This entry is correct, and we cannot update Preclarus at the site level' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	17 Mar 2021 15:01:30
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 27Oct2020 is reported under Illness Visit Day 9 in EDC, however same is reported for Day 28 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:24:28
User closed query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 27OCT2020 recorded under Illness Visit Days 3-21, however, per Viracor, the Saliva sample with a Collection Date of 27OCT2020 is recorded under an Unscheduled Visit. Please confirm the correct Visit Name in the query response, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 18:50:45
Query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 27OCT2020 recorded under Illness Visit Days 3-21, however, per Viracor, the Saliva sample with a Collection Date of 27OCT2020 is recorded under an Unscheduled Visit. Please confirm the correct Visit Name in the query response, as appropriate. ' answered with 'only an unscheduled kit was available' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	12 Jan 2021 19:39:35

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:26:31

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 27OCT2020 recorded under Illness Visit Days 3-21, however, per Viracor, the Saliva sample with a Collection Date of 27OCT2020 is recorded under an Unscheduled Visit. Please confirm the correct Visit Name in the query response, as appropriate. ' (Site from DM). User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6) (b) (4)	08 Jan 2021 21:04:29
	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:26:31

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per source, saliva sample was collected on 27-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:20:24
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:17
Query 'Per source, saliva sample was collected on 27-Oct-2020. Please review and reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:17:56
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:17:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:17:49
User opened query 'Per source, saliva sample was collected on 27-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:56:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:30:54
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:14:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:17:49
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:17:49
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:30:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:26:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 30Oct2020 is reported under Illness Visit Day 14 in EDC, however same is reported for Day 1 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:05:32
Query 'Per GCL Lab Recon: Saliva: Sample dated 30Oct2020 is reported under Illness Visit Day 14 in EDC, however same is reported for Day 1 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' answered with 'This entry is correct, and we cannot update Preclarus at the site level' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	17 Mar 2021 15:01:40
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 30Oct2020 is reported under Illness Visit Day 14 in EDC, however same is reported for Day 1 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:25:26
User accepted default value 'Day 14 (Day 14)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:26:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Please ensure data is listed in source. No documentation of saliva sample being collected on 30-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:25:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:25:08
Query 'Please ensure data is listed in source. No documentation of saliva sample being collected on 30-Oct-2020. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:07:26
User opened query 'Please ensure data is listed in source. No documentation of saliva sample being collected on 30-Oct-2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 21:27:48
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:28:07
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:27
User closed query 'please verify as 30Oct2020 per source' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:55:08
User closed query 'Per GCL Lab Recon:LB3 Saliva: Per GCL, this sample is updated under "30 OCT 2020", however here it is updated under "31 OCT 2020",Please review the Preclarus PPD portal and confirm the correct visit label and sample collection date for this Illness visit day 14 saliva sample.Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 11:52:55
Query 'please verify as 30Oct2020 per source' answered with 'Updated to 30 OCT 2020' (Site from CRA).	Haylee Rowe (b) (4) (b) (4)	11 Mar 2021 20:32:22
Query 'Per GCL Lab Recon:LB3 Saliva: Per GCL, this sample is updated under "30 OCT 2020", however here it is updated under "31 OCT 2020",Please review the Preclarus PPD portal and confirm the correct visit label and sample collection date for this Illness visit day 14 saliva sample.Thank you. ' answered with 'Updated to 30 OCT 2020' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	11 Mar 2021 20:32:03
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	11 Mar 2021 20:31:48
User entered '30 Oct 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	11 Mar 2021 20:31:48
User opened query 'please verify as 30Oct2020 per source' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 18:00:12
User opened query 'Per GCL Lab Recon:LB3 Saliva: Per GCL, this sample is updated under "30 OCT 2020", however here it is updated under "31 OCT 2020",Please review the Preclarus PPD portal and confirm the correct visit label and sample collection date for this Illness visit day 14 saliva sample.Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:26:29

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Recon: Saliva: Per GCL, this sample is updated under "30 OCT 2020", however here it is updated under '31 OCT 2020',Please review the Preclarus PPD portal and confirm the correct visit label and sample collection date for this Illness visit day 14 saliva sample.Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:26:08
User opened query 'Per GCL Lab Recon: Saliva: Per GCL, this sample is updated under "30 OCT 2020", however here it is updated under '31 OCT 2020',Please review the Preclarus PPD portal and confirm the correct visit label and sample collection date for this Illness visit day 14 saliva sample.Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:25:59
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:43:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F621605922' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	24 Feb 2021 20:46:52
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 05:28:52

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 30OCT2020 is reported under Illness Visit Day 14 in EDC, however same is reported for Illness Visit Day 1 in PPD central lab. Please confirm the correct visit, Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	15 Feb 2021 05:28:13
	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
Query 'Per GCL Lab Recon: Saliva: Sample dated 30OCT2020 is reported under Illness Visit Day 14 in EDC, however same is reported for Illness Visit Day 1 in PPD central lab. Please confirm the correct visit, Thank you.' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4)	05 Feb 2021 19:23:16
	(b) (4)	
DataPoint Un-verified.	Jamie Pettus (b) (4)	05 Feb 2021 19:23:08
	(b) (4)	
User entered '31 Oct 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4)	05 Feb 2021 19:23:08
	(b) (4)	
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 30OCT2020 is reported under Illness Visit Day 14 in EDC, however same is reported for Illness Visit Day 1 in PPD central lab. Please confirm the correct visit, Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 06:56:27
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please review the preclaus data and update the sample dated 30OCT2020 to correct visit and confirm the correct visit in query response.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 05:37:05
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please review the preclaus data and update the sample dated 30OCT2020 to correct visit and confirm the correct visit in query response.' answered with 'data changed' (Site from DM).	Jamie Pettus (b) (4)	19 Jan 2021 17:03:06
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please review the preclaus data and update the sample dated 30OCT2020 to correct visit and confirm the correct visit in query response.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 06:23:29

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Per GCL, sample with Collection Date of 30OCT2020 is recorded under Illness Visit Day 1, however, here the Saliva sample with a Collection Date of 30OCT2020 is recorded under Illness Visit Day 14. Please confirm the correct Visit Name in the query response, as appropriate.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Per GCL, sample with Collection Date of 30OCT2020 is recorded under Illness Visit Day 1, however, here the Saliva sample with a Collection Date of 30OCT2020 is recorded under Illness Visit Day 14. Please confirm the correct Visit Name in the query response, as appropriate.' answered with 'only the day 28 visit was done due to illness at the time and distance of travel; saliva samples were collected however' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 06:23:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Per GCL, sample with Collection Date of 30OCT2020 is recorded under Illness Visit Day 1, however, here the Saliva sample with a Collection Date of 30OCT2020 is recorded under Illness Visit Day 14. Please confirm the correct Visit Name in the query response, as appropriate.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	Jamie Pettus (b) (4) (b) (4)	12 Jan 2021 19:41:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Per GCL, sample with Collection Date of 30OCT2020 is recorded under Illness Visit Day 1, however, here the Saliva sample with a Collection Date of 30OCT2020 is recorded under Illness Visit Day 14. Please confirm the correct Visit Name in the query response, as appropriate.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 19:03:32
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 19:02:20
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 04:30:45
	(b) (4), (b) (6)	10 Nov 2020 17:25:10

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EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 17:22:11
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:07:18
User entered '30 Oct 2020'	Amanda Horn (b) (4)	30 Oct 2020 15:14:31

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:26:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User accepted default value 'Day 21 (Day 21)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:26:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:29:16
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 15:25:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 15:25:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 15:25:06
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:14:31
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose, once the data is updated in preclaus to correct to subject ID and correct visit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 04:43:40
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose, once the data is updated in preclaus to correct to subject ID and correct visit. ' answered with '914897883910' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	20 Jan 2021 14:58:11
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose, once the data is updated in preclaus to correct to subject ID and correct visit. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 05:35:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 05:35:57

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'scanned in under someone else in Preclarus; under US3752084; APRN has open ticket with investigator service; helpdesk; 1f621605922 under date 30-Oct-2020' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	12 Jan 2021 20:03:24
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:31:07
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:29:17
User entered '6 Nov 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 15:25:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:26:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
User accepted default value 'Day 28 (Day 28)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:26:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 18:00:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 18NOV2020 under Convalescence Visit Day 28 is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 06:33:41
Query 'Per GCL Lab Recon: Saliva: Sample dated 18NOV2020 under Convalescence Visit Day 28 is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' answered with 'completed per source docs' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	12 Jan 2021 19:43:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	12 Jan 2021 19:43:08
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 18NOV2020 under Convalescence Visit Day 28 is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:54:58
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	09 Nov 2020 10:13:40
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:14:31
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:14:31

US3752162

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:25
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 18:00:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '18 Nov 2020' reason for change: Data Entry Error	(b) (4)	12 Jan 2021 19:43:08
User entered empty.	Jamie Pettus (b) (4)	12 Jan 2021 19:43:08
	(b) (4)	
	Amanda Horn (b) (4)	30 Oct 2020 15:14:31
	(b) (4)	

US3752162

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:33:12
User closed query 'Per CDM: Per sponsor review, it appears this may be Convalescence Visit D28. Please confirm if the visit from 18Nov2020 is Convalescence Visit Day 28. If confirmed, please remove record Illness Visit Day 1 as not performed (per previous query responses) and update Convalescence Day 28 as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 09:10:10
User closed query 'Based on previous query response this page should be answered NO on the first question and all other questions should remain blank.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 12:40:10
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:49
Query 'Based on previous query response this page should be answered NO on the first question and all other questions should remain blank.' answered with 'CORRECTED. ILLNESS VISIT 1 WAS NOT PERFORMED' (Site from CRA).	(b) (4) Amanda Horn (b) (4)	09 Apr 2021 15:01:17
Signature has been broken.	Amanda Horn (b) (4)	09 Apr 2021 15:00:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Amanda Horn (b) (4)	09 Apr 2021 15:00:41
User opened query 'Based on previous query response this page should be answered NO on the first question and all other questions should remain blank.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 23:57:28
Query 'Per CDM: Per sponsor review, it appears this may be Convalescence Visit D28. Please confirm if the visit from 18Nov2020 is Convalescence Visit Day 28. If confirmed, please remove record Illness Visit Day 1 as not performed (per previous query responses) and update Convalescence Day 28 as appropriate. Thank you. ' answered with 'subject never made it into the clinic for Illness visit Day 1, but saliva samples were collected. Please advise on what date should be used for Illness visit Day 1' (Site from DM).	Lauren Evans (b) (4)	07 Apr 2021 14:33:45

US3752162

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per sponsor review, it appears this may be Convalescence Visit D28. Please confirm if the visit from 18Nov2020 is Convalescence Visit Day 28. If confirmed, please remove record Illness Visit Day 1 as not performed (per previous query responses) and update Convalescence Day 28 as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 19:00:02
User closed query 'Please complete D28 Convalescent Visit tab for 18Nov2020 as per source' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:42:31
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
Query 'Please complete D28 Convalescent Visit tab for 18Nov2020 as per source' answered with 'Data entered' (Site from CRA).	Jamie Pettus (b) (4)	15 Mar 2021 16:44:23
User opened query 'Please complete D28 Convalescent Visit tab for 18Nov2020 as per source' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 21:02:42
User closed query 'Please complete D28 Convalescent Visit tab for 18Nov2020 as per source' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 21:02:42
Query 'Please complete D28 Convalescent Visit tab for 18Nov2020 as per source' answered with 'updated' (Site from CRA).	Jamie Pettus (b) (4)	12 Mar 2021 17:10:00
Signature has been broken.	Jamie Pettus (b) (4)	12 Mar 2021 17:09:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	12 Mar 2021 17:09:52
User opened query 'Please complete D28 Convalescent Visit tab for 18Nov2020 as per source' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 18:10:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06

US3752162

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: SARS-CoV-2: Re-query: Response noted as "SARS sample" not collected, however, there it is still reflecting in PPD GCL under Convalescence Visit Day 28 with sample collection date of 18 NOV 2020 and GCL lab panel name of "SARS CoV2 8". Please kindly review the Preclarus and send a DCF to PPD GCL to remove the record of the SARS sample dated 18 NOV 2020, to avoid this confusion and provide response when it is updated correctly in Preclarus accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 06:04:19
Query 'Per GCL Lab Recon: SARS-CoV-2: Re-query: Response noted as "SARS sample" not collected, however, there it is still reflecting in PPD GCL under Convalescence Visit Day 28 with sample collection date of 18 NOV 2020 and GCL lab panel name of "SARS CoV2 8". Please kindly review the Preclarus and send a DCF to PPD GCL to remove the record of the SARS sample dated 18 NOV 2020, to avoid this confusion and provide response when it is updated correctly in Preclarus accordingly. Thank you.' answered with 'I don't understand why we would ask to have it removed. It was part of Illness day 28. Your instructions are not clear. please clarify and BE SPECIFIC.' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 16:51:52
User opened query 'Per GCL Lab Recon: SARS-CoV-2: Re-query: Response noted as "SARS sample" not collected, however, there it is still reflecting in PPD GCL under Convalescence Visit Day 28 with sample collection date of 18 NOV 2020 and GCL lab panel name of "SARS CoV2 8". Please kindly review the Preclarus and send a DCF to PPD GCL to remove the record of the SARS sample dated 18 NOV 2020, to avoid this confusion and provide response when it is updated correctly in Preclarus accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 16:54:59

US3752162

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: SARS-CoV-2 sample: Re-query: Response noted, Please kindly clarify in the response, if there is any SARS sample collected on 18 NOV 2020. If it is not collected, then please kindly review Preclarus data and confirm the correct subject ID and visit label, for which this SARS sample has been collected, to which this Subject ID does this SARS sample belongs and update in EDC and Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 16:54:59
Query 'Per GCL Lab Recon: SARS-CoV-2 sample: Re-query: Response noted, Please kindly clarify in the response, if there is any SARS sample collected on 18 NOV 2020. If it is not collected, then please kindly review Preclarus data and confirm the correct subject ID and visit label, for which this SARS sample has been collected, to which this Subject ID does this SARS sample belongs and update in EDC and Preclarus as appropriate. Thank you.' answered with 'Visit was not performed because of the long distance, positive COVID results, the saliva PCR was taken on the date mentioned and it was taken there in the patient's home over (b) (6) away by car' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	21 Jan 2021 16:37:49
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	21 Jan 2021 16:33:24
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	21 Jan 2021 16:33:24
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	21 Jan 2021 16:31:13
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	21 Jan 2021 16:31:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	21 Jan 2021 16:31:13

US3752162

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: SARS-CoV-2 sample: Re-query: Response noted, Please kindly clarify in the response, if there is any SARS sample collected on 18 NOV 2020. If it is not collected, then please kindly review Preclarus data and confirm the correct subject ID and visit label, for which this SARS sample has been collected, to which this Subject ID does this SARS sample belongs and update in EDC and Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:03:14
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 NOV 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:03:14
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 NOV 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' answered with 'Only one visit done due to long distance an COVID illness; saliva samples take though' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	12 Jan 2021 20:04:59
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 NOV 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 09:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:22:19
Query 'Re-query: Per protocol this is to be a clinic visit or home visit with a swab collected. Please verify why courier used.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 03:55:32

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Re-query: Per protocol this is to be a clinic visit or home visit with a swab collected. Please verify why courier used.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 00:36:41
User closed query 'Please verify how saliva sample was collected. If home visit completed this page should reflect that. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 00:36:41
Query 'Please verify how saliva sample was collected. If home visit completed this page should reflect that. ' answered with 'SALIVA SAMPLE COLLECTED VIA COURIER. PHYSICAL EXAM NOT COMPLETED. ' (Site from CRA).	Amanda Horn (b) (4)	03 Nov 2020 14:31:28
User opened query 'Please verify how saliva sample was collected. If home visit completed this page should reflect that. ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 02:35:28
User entered 'No (N)'	Amanda Horn (b) (4)	30 Oct 2020 15:13:31

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:33:12
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:49
Signature has been broken.	(b) (4)	09 Apr 2021 15:00:41
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4)	09 Apr 2021 15:00:41
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
DataPoint Un-verified.	(b) (4)	12 Mar 2021 17:09:52
Signature has been broken.	Jamie Pettus (b) (4)	12 Mar 2021 17:09:52
User entered '18 Nov 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4)	12 Mar 2021 17:09:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	09 Nov 2020 21:22:19
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 15:13:31
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:33:12
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:49
Signature has been broken.	(b) (4)	09 Apr 2021 15:00:41
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4)	09 Apr 2021 15:00:41
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
DataPoint Un-verified.	Jamie Pettus (b) (4)	12 Mar 2021 17:09:52
Signature has been broken.	Jamie Pettus (b) (4)	12 Mar 2021 17:09:52
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	12 Mar 2021 17:09:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	21 Jan 2021 16:33:24
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	21 Jan 2021 16:31:13
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:22:19
User entered empty.	Amanda Horn (b) (4)	30 Oct 2020 15:13:31

US3752162

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	30 Oct 2020 15:13:31

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:23
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:49
	(b) (4)	
Signature has been broken indirectly.	System	09 Apr 2021 15:00:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:22:23
User entered empty.	Amanda Horn (b) (4)	30 Oct 2020 15:13:40
	(b) (4)	

US3752162

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:13:40

US3752162

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:28
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:44

US3752162

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:44

US3752162

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:26:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User closed query 'Per Lab Recon: SARS-CoV2: Per Preclarus report, Sample dated "18 NOV 2020" is reported in Illness D28 [1] in PPD GCL, however the same is missing in EDC. Please update the details under Convalescence Visit Day 28 in this Illness visit folder. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Priyantha Wijewardane	23 Feb 2021 11:54:57 12 Feb 2021 18:37:06
Query 'Per Lab Recon: SARS-CoV2: Per Preclarus report, Sample dated "18 NOV 2020" is reported in Illness D28 [1] in PPD GCL, however the same is missing in EDC. Please update the details under Convalescence Visit Day 28 in this Illness visit folder. Thank you.' answered with 'that visit wasn't done due to the patient's accident and distance; kits were delivered to them and picked up after specimens taken by patient at home; they were shipped on 18 NOV 2020' (Site from DM).	(b) (4) Jamie Pettus (b) (4) (b) (4)	05 Feb 2021 17:10:38
User opened query 'Per Lab Recon: SARS-CoV2: Per Preclarus report, Sample dated "18 NOV 2020" is reported in Illness D28 [1] in PPD GCL, however the same is missing in EDC. Please update the details under Convalescence Visit Day 28 in this Illness visit folder. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Feb 2021 11:54:40 09 Nov 2020 21:22:30
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:48

US3752162

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:13:48

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:50
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:01:04
User closed query 'Please verify as other visit assessments are present.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 12:40:17
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:49
Query 'Please verify as other visit assessments are present.' answered with 'VISIT WAS COMPLETED' (Site from CRA).	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	09 Apr 2021 14:59:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 14:59:36
User opened query 'Please verify as other visit assessments are present.' (Site from CRA).	Amanda Horn (b) (4)	09 Apr 2021 14:59:36
User signature succeeded.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 23:57:59
	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
	Jamie Pettus (b) (4)	15 Mar 2021 16:41:06
	(b) (4)	

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:50
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:01:04
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:49
Signature has been broken.	(b) (4)	
	Amanda Horn (b) (4)	09 Apr 2021 14:59:36
User entered '18 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	09 Apr 2021 14:59:36
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	15 Mar 2021 16:41:06
	(b) (4)	

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:50
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:01:04
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:49
Signature has been broken.	(b) (4)	
	Amanda Horn (b) (4)	09 Apr 2021 14:59:36
User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	09 Apr 2021 14:59:36
User signature succeeded.	(b) (4)	
	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	15 Mar 2021 16:41:06
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:50
User entered 'SICKD28'	System	15 Mar 2021 16:41:06

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:00:06
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered 'Yes (Y)'	Jamie Pettus (b) (4)	15 Mar 2021 16:45:13
	(b) (4)	

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:00:06
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered '18 Nov 2020'	Jamie Pettus (b) (4)	15 Mar 2021 16:45:13
	(b) (4)	

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:00:06
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered '11:19'	Jamie Pettus (b) (4)	15 Mar 2021 16:45:13
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
User entered '18 Nov 2020 11:19'	System	15 Mar 2021 16:45:13

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint set to visible.	System	09 Apr 2021 14:59:36

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint set to visible.	System	09 Apr 2021 14:59:36

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:00:06
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered '97.6' F	Jamie Pettus (b) (4)	15 Mar 2021 16:45:13
	(b) (4)	

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:00:06
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered 'Oral (Oral)'	Jamie Pettus (b) (4)	15 Mar 2021 16:45:13
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:00:06
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	15 Mar 2021 16:45:13
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:00:06
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered '64'	Jamie Pettus (b) (4)	15 Mar 2021 16:45:13
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
User entered 'bpm'	System	15 Mar 2021 16:45:13

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:00:06
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered '18'	Jamie Pettus (b) (4)	15 Mar 2021 16:45:13
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
User entered 'breaths/min'	System	15 Mar 2021 16:45:13

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:00:06
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered '138'	Jamie Pettus (b) (4)	15 Mar 2021 16:45:13
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
User entered 'mmHg'	System	15 Mar 2021 16:45:13

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:00:06
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
	(b) (4)	
User entered '88'	Jamie Pettus (b) (4)	15 Mar 2021 16:45:13
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44
User entered 'mmHg'	System	15 Mar 2021 16:45:13

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Weight (derived)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:08:51
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:44

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:59:20
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
User entered 'Yes (Y)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	15 Mar 2021 16:45:34

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:59:20
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '18 Nov 2020' reason for change: Data Entry Error	System	15 Mar 2021 16:45:41
User opened query 'Future date has been entered. Please correct.' (Site from System).	Jamie Pettus (b) (4)	15 Mar 2021 16:45:41
User entered '18 Nov 2021'	(b) (4)	
	System	15 Mar 2021 16:45:34
	Jamie Pettus (b) (4)	15 Mar 2021 16:45:34
	(b) (4)	

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:26:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:34
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:37:57
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
User entered 'Yes (Y)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	15 Mar 2021 16:46:04

US3752162

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:26:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:34
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:37:57
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:46
User entered '18 Nov 2020'	(b) (4) Jamie Pettus (b) (4) (b) (4)	15 Mar 2021 16:46:04

US3752162

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

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:47:26

US3752162

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

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:47:26

US3752162

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

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:47:26

US3752162

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

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 20:47:26

US3752162

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:48:04

US3752162

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	22 Apr 2021 15:21:44
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:19:18
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:51:32

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:48:04

US3752162

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:14:55
User signature succeeded.	Priyantha Wijewardane	22 Apr 2021 15:21:44
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'data updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:38
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 14:19:18
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 05:59:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:51:32

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:48:04

US3752162

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:48:04

US3752162

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 02:46:04
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	18 Jan 2021 20:48:04

US3752162

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 02:46:04
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	18 Jan 2021 20:48:04

US3752162

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:48:04

US3752162

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered '1'	System	18 Jan 2021 20:48:04

US3752162

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

Form: Unblinding

Generated On: 12 Aug 2021 13:26:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'I'	System	18 Jan 2021 20:48:04

US3752162

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '172.2' cm	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '95.5' kg	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered '32.20602'	System	18 Jan 2021 20:49:37
DataPoint set to visible.	System	18 Jan 2021 20:48:04

US3752162

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '172.2' cm	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '95.5' kg	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered '32.20602'	System	18 Jan 2021 20:49:37
DataPoint set to visible.	System	18 Jan 2021 20:48:04

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '10:10'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered '18 Jan 2021 10:10'	System	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Oral (Oral)'	(b) (4)	18 Jan 2021 20:49:37
	(b) (4), (b) (6)	

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '67'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'bpm'	System	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '14'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'breaths/min'	System	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '132'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'mmHg'	System	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '78'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'mmHg'	System	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '172.2' cm	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '95.5' kg	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:26:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered '32.20602'	System	18 Jan 2021 20:49:37
DataPoint set to visible.	System	18 Jan 2021 20:48:04

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '11:16'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered '18 Jan 2021 11:16'	System	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	18 Jan 2021 20:49:37
	(b) (4), (b) (6)	

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '65'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'bpm'	System	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'breaths/min'	System	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '130'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'mmHg'	System	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '78'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:37

US3752162

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'mmHg'	System	18 Jan 2021 20:49:37

US3752162

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:46

US3752162

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '18 Jan 2021'	(b) (4)	18 Jan 2021 20:49:46
	(b) (4), (b) (6)	

US3752162

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

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:58

US3752162

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

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:58

US3752162

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

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

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)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:58

US3752162

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

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'mRNA-1273'	System	18 Jan 2021 20:49:58
DataPoint set to visible.	System	18 Jan 2021 20:48:04

US3752162

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

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:58

US3752162

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

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '10:46'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:58

US3752162

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

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered '18 Jan 2021 10:46'	System	18 Jan 2021 20:49:58

US3752162

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

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:49:58

US3752162

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

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'ONCE'	System	18 Jan 2021 20:49:58

US3752162

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

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered 'INTRAMUSCULAR'	System	18 Jan 2021 20:49:58

US3752162

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:50:13

US3752162

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:50:13

US3752162

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '10:24'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:50:13

US3752162

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered '18 Jan 2021 10:24'	System	18 Jan 2021 20:50:13

US3752162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:06:42

US3752162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:06:42

US3752162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:26:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '10:27'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:06:42

US3752162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:26:31

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered '18 Jan 2021 10:27'	System	18 Jan 2021 21:06:42

US3752162

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

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:06:46

US3752162

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

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:51
User entered '1'	System	18 Jan 2021 21:06:46

US3752162

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:29:30

US3752162

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:29:30

US3752162

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:29:30

US3752162

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:29:30

US3752162

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:29:35

US3752162

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User entered 'I'	System	26 Jan 2021 15:29:35

US3752162

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User entered '1'	System	26 Jan 2021 15:29:35
DataPoint set to visible.	System	26 Jan 2021 15:29:35

US3752162

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 20:31:52
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '24 Feb 2021'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:31:52
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Clinic (Clinic)'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:31:52
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'OLD29'	System	24 Feb 2021 20:31:52

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User accepted default value 'Pre-Dose (PREDOSE)'	Haylee Rowe (b) (4) (b) (4)	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 20:33:44
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '24 Feb 2021'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '11:05'	(b) (4)	24 Feb 2021 20:33:44
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered '24 Feb 2021 11:05'	System	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '98.2' F	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Oral (Oral)'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	24 Feb 2021 20:33:44
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '71'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'bpm'	System	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '16'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'breaths/min'	System	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '122'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'mmHg'	System	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '76'	(b) (4) Haylee Rowe (b) (4) (b) (4)	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'mmHg'	System	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User accepted default value 'Post-Dose (POSTDOSE)'	Haylee Rowe (b) (4) (b) (4)	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 20:33:44
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '24 Feb 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '11:52'	(b) (4)	24 Feb 2021 20:33:44
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered '24 Feb 2021 11:52'	System	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '98.9' F	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Oral (Oral)'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	24 Feb 2021 20:33:44
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '72'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'bpm'	System	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '15'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'breaths/min'	System	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '118'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:44
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'mmHg'	System	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '70'	(b) (4) Haylee Rowe (b) (4) (b) (4)	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'mmHg'	System	24 Feb 2021 20:33:44

US3752162

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 20:33:57
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '24 Feb 2021'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:33:57
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	24 Feb 2021 20:34:21

US3752162

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:34:21
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

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)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	24 Feb 2021 20:34:21
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'mRNA-1273'	System	24 Feb 2021 20:34:21
DataPoint set to visible.	System	26 Jan 2021 15:29:35

US3752162

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '24 Feb 2021'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:34:21
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '11:22'	(b) (4)	
	Haylee Rowe (b) (4)	24 Feb 2021 20:34:21
	(b) (4)	

US3752162

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered '24 Feb 2021 11:22'	System	24 Feb 2021 20:34:21

US3752162

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	24 Feb 2021 20:34:21

US3752162

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'ONCE'	System	24 Feb 2021 20:34:21

US3752162

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:26:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 20:34:21

US3752162

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	24 Feb 2021 20:34:28

US3752162

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:45:25
User entered 'I'	System	24 Feb 2021 20:34:28

US3752162

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	
	Amanda Horn (b) (4)	04 Mar 2021 17:14:52
	(b) (4)	

US3752162

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '3 Mar 2021'	(b) (4)	
	Amanda Horn (b) (4)	04 Mar 2021 17:14:52
	(b) (4)	

US3752162

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Mar 2021 17:14:52

US3752162

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:26:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	04 Mar 2021 17:14:52
	(b) (4)	

US3752162

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Yes (Y)'	(b) (4)	
	Amanda Horn (b) (4)	04 Mar 2021 17:14:56
	(b) (4)	

US3752162

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:26:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:44
User entered 'I'	System	04 Mar 2021 17:14:56

US3752162

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:26

US3752162

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:26

US3752162

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:26

US3752162

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:26:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User entered 'OLD57'	System	24 Mar 2021 16:50:26

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '11:07'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User entered '24 Mar 2021 11:07'	System	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '72'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User entered 'bpm'	System	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User entered 'breaths/min'	System	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '104'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User entered 'mmHg'	System	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '72'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User entered 'mmHg'	System	24 Mar 2021 16:50:51

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40

US3752162

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:26:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40

US3752162

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:50:59

US3752162

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:26:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '24 Mar 2021'	(b) (4)	24 Mar 2021 16:50:59
	(b) (4), (b) (6)	

US3752162

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:51:27

US3752162

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:51:27

US3752162

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '11:15'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:51:27

US3752162

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:26:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:40
User entered '24 Mar 2021 11:15'	System	24 Mar 2021 16:51:27

US3752162

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:26:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:39:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 02:17:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 18:38:38
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:37:00

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 23:49:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 23:49:53
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:25:55
Data point term sent to Coder	System	19 Nov 2020 17:24:26
Coding entries removed.	(b) (4), (b) (6)	19 Nov 2020 17:23:52
User entered 'FRACTURED FOOT(Right)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:23:52
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 20:36:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 20:36:31
Data point term sent to Coder	System	14 Oct 2020 18:41:53
User entered 'FRACTURED FOOT'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:25:58
User entered 'Yes (Y)'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:03
User entered 'No (N)'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:09
User entered 'No (N)'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:13
User entered '16 Sep 2020'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:18
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 08:16:48
Query 'Data is required. Please provide.' answered with 'UNKNOWN START TIME. OCCURRED AFTER INJECTION ' (Site from System).	Amanda Horn (b) (4)	14 Oct 2020 18:41:34
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 18:41:08
User entered empty.	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User entered empty.	System	14 Oct 2020 18:41:08

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
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. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Jan 2021 13:01:21
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 20:48:59
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 20:48:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 20:48:51
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 02:24:05
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:22
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 18:41:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Mar 2021 18:46:27
User entered '01 Dec 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4)	26 Mar 2021 18:46:27
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Mar 2021 18:44:56
Signature has been broken.	Haylee Rowe (b) (4)	26 Mar 2021 18:44:56
	(b) (4)	
User entered 'UN Dec 2020' (non-conformant).	Haylee Rowe (b) (4)	26 Mar 2021 18:44:56
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 20:48:51
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:24
User entered empty.	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Jan 2021 13:01:23
Query 'Data is required. Please provide.' answered with 'end time unknown' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 20:49:07
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Dec 2020 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:27
User entered empty.	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User entered empty.	System	14 Oct 2020 18:41:08

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:36
User entered 'No (N)'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:38
User entered '0'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:40
User entered '0'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:43
User entered '0'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:46
User entered empty.	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:48
User entered empty.	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:53
User entered empty.	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:57
User entered empty.	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:59
User entered '0'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:27:02
User entered '0'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:27:05
User entered '0'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:27:08
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:27:11
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:27:13
User entered 'None (NONE)'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:27:17
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:52:10
User entered '0'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:27:19
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 20:59:02
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:52:18
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:52:10
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:54:49
User entered '1'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:27:32
User entered '0'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 20:48:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	30 Dec 2020 20:48:51
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:27:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:28:41
User entered empty.	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:28:43
User entered empty.	Amanda Horn (b) (4)	14 Oct 2020 18:41:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User entered '0'	System	14 Oct 2020 18:41:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14
User entered '1'	System	14 Oct 2020 18:41:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:33:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:39
User entered	System	02 Nov 2020 14:16:34
'USA-US113-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	02 Nov 2020 14:16:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 01:17:33
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)	23 Nov 2020 21:39:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:39:03
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 16:01:35
User closed query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System).	System	23 Nov 2020 16:01:19
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:01:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:01:12
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 16:01:12
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 16:01:12
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 12:24:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:50:25
User closed query 'Per CCG v2.0 pg. 51, AE term should be entered as Symptomatic COVID-19. Please correct entry in eCRF and ensure source and eCRF match.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:50:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
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)	10 Nov 2020 14:28:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:28:31
Data point term sent to Coder	System	10 Nov 2020 14:27:59
Query 'Per CCG v2.0 pg. 51, AE term should be entered as Symptomatic COVID-19. Please correct entry in eCRF and ensure source and eCRF match.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 14:27:18
Coding entries removed.	(b) (4), (b) (6)	10 Nov 2020 14:27:10
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 14:27:10
User opened query 'Per CCG v2.0 pg. 51, AE term should be entered as Symptomatic COVID-19. Please correct entry in eCRF and ensure source and eCRF match.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 21:33:21
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)	08 Nov 2020 17:48:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Nov 2020 17:48:32
Data point term sent to Coder	System	08 Nov 2020 17:47:41
User closed query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' (Site from System).	System	08 Nov 2020 17:47:34
Query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' answered with 'UPDATED' (Site from System).	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 17:47:34
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 17:46:58
User entered 'COVID-19 INFECTION' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 17:46:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' (Site from System).	Coder Import (b) (4)	07 Nov 2020 18:24:48
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 15:19:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 15:19:53
Data point term sent to Coder	System	30 Oct 2020 15:19:28
User entered 'COVID-19 POSITIVE'	Amanda Horn (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:33:53
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:34
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 02:17:48
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:34:16
User entered '17 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:34:18
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Oct 2020 15:19:05
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4)	30 Oct 2020 15:19:05
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Oct 2020 15:18:49
User entered '08:00'	Amanda Horn (b) (4)	30 Oct 2020 15:18:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:19:05
User entered '17 Oct 2020 08:00'	System	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:34:20
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 15:41:12
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	30 Oct 2020 15:18:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:34:22
User entered '2 Nov 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 15:41:12
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	30 Oct 2020 15:18:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:34:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:34:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:34:53
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 22:05:14
User entered '0'	Amanda Horn (b) (4)	30 Oct 2020 15:18:49
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:15
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:17
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:19
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:21
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:24
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:34:43
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:34:44
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:34:48
User closed query 'PV Query: As the last dose of study drug was given on 16 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 13:53:02
Query 'PV Query: As the last dose of study drug was given on 16 Sep 2020, please update the action taken with study drug from none to not applicable.'	Amanda Horn (b) (4) (b) (4)	06 Nov 2020 18:42:41
answered with 'UPDATED' (Site from Safety).		
User entered 'Not Applicable (NOT APPLICABLE)'	Amanda Horn (b) (4) (b) (4)	06 Nov 2020 18:42:32
reason for change: Data Entry Error		
User opened query 'PV Query: As the last dose of study drug was given on 16 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:46:17
User entered 'None (NONE)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 22:05:02
User entered '0'	Amanda Horn (b) (4)	30 Oct 2020 15:18:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:03
User closed query 'Per CDM: ConMed is checked as Yes. Please clarify CM log line number is associated with this AE or provide CM if missing. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 20:59:12
Query 'Per CDM: ConMed is checked as Yes. Please clarify CM log line number is associated with this AE or provide CM if missing. ' answered with 'THERE ARE 3 MEDICATIONS LISTED FOR COVID SYMPTOMS IN CON MEDS' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:04:06
User opened query 'Per CDM: ConMed is checked as Yes. Please clarify CM log line number is associated with this AE or provide CM if missing. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:42:38
User entered 'I'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 22:05:05
User entered '0'	Amanda Horn (b) (4)	30 Oct 2020 15:18:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:34:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 15:41:12
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:05:08
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:50:50
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 15:59:03
User entered 'KNOWN EXPOSURE 07OCT2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 15:59:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:35
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 13:53:09
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19.' answered with 'UPDATED' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	06 Nov 2020 18:42:47
User entered 'KNOWN EXPOSURE 13OCT2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	06 Nov 2020 18:42:32
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:46:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 15:18:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 15:18:49

US3752162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:26:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 15:18:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:17:26
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'in this case it was agitated by the motor vehicle accident, not a worenig' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	21 Jan 2021 16:14:02
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 06:24:46
User closed query 'Per DM CLR: Please review and remove the surgery/procedure from the AE term as it is already recorded in the Concomitant Procedure eCRF and only record the underlying medical condition. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 10:30:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 20:51:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 20:51:20
Data point term sent to Coder	System	30 Dec 2020 20:50:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and remove the surgery/procedure from the AE term as it is already recorded in the Concomitant Procedure eCRF and only record the underlying medical condition. Update as appropriate. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 20:50:00
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 20:49:52
Coding entries removed.	(b) (4), (b) (6)	30 Dec 2020 20:49:52
User entered 'LOW BACK PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 20:49:52
User opened query 'Per DM CLR: Please review and remove the surgery/procedure from the AE term as it is already recorded in the Concomitant Procedure eCRF and only record the underlying medical condition. Update as appropriate.'	(b) (4), (b) (6)	12 Dec 2020 12:28:09
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:19:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 06:33:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	19 Nov 2020 06:33:54
Data point term sent to Coder	System	18 Nov 2020 20:17:25
Coding entries removed.	(b) (4), (b) (6)	18 Nov 2020 20:16:27
User entered 'L5 S1 DISCECTOMY WITH RIGHT LATERAL HEMILAMINECTOMY due to low back pain' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 20:16:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 20:14:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	18 Nov 2020 20:14:48

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	18 Nov 2020 20:14:23
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 20:14:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 20:14:00
User closed query 'CDM CODING: Please specify only the underlying medical condition for the reported procedure.' (Site from System).	System	18 Nov 2020 20:13:24
Query 'CDM CODING: Please specify only the underlying medical condition for the reported procedure.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 20:13:24
Data point term sent to Coder	System	18 Nov 2020 20:13:21
User entered 'Low back pain' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 20:13:14
User opened query 'CDM CODING: Please specify only the underlying medical condition for the reported procedure.' (Site from System).	Coder Import (b) (4)	12 Nov 2020 04:02:40
Data point term sent to Coder	System	06 Nov 2020 15:55:25
User entered 'L5 S1 Discectomy with right lateral hemilaminectomy'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:19:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:20:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:20:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:20:06
User entered '15 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:20:10
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User entered empty.	System	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:20:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:20:17
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	06 Nov 2020 15:55:29
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	06 Nov 2020 15:55:29
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	06 Nov 2020 15:55:12
User entered '15 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:31
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User entered empty.	System	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User closed query 'Per source grade is 2/moderate. Please updated EDC or clarify.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Priyantha Wijewardane	23 Feb 2021 05:01:52 12 Feb 2021 18:37:06
Query 'Per source grade is 2/moderate. Please updated EDC or clarify.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 20:50:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 20:49:52
User opened query 'Per source grade is 2/moderate. Please updated EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	30 Nov 2020 21:19:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 21:19:39
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:36
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:38
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:39
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:41
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:44
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:47
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:49
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:50
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:52
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:55
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:21:58
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:22:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:22:03
User entered 'None (NONE)'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Un-verified.	Jamie Pettus (b) (4)	01 Feb 2021 15:34:43
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Feb 2021 15:34:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:22:09
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:22:14
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is indicated for MEDICAL HISTORY rather than for AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	02 Feb 2021 03:40:46
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is indicated for MEDICAL HISTORY rather than for AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4)	01 Feb 2021 15:34:54
DataPoint Un-verified.	(b) (4)	01 Feb 2021 15:34:43
User entered '0' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Feb 2021 15:34:43
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is indicated for MEDICAL HISTORY rather than for AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:57:21
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:22:17
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:22:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	06 Nov 2020 15:55:29
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:22:22
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:22:28
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User entered '0'	System	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17
User entered '1'	System	06 Nov 2020 15:55:12

US3752162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:17

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:29:38
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 19:34:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 19:34:47
	(b) (4)	
Data point term sent to Coder	System	18 Nov 2020 19:34:27
User entered 'Motor Vehicle Accident'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:29:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:29:42
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:29:44
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:29:47
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 15:13:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 15:13:10
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 15:13:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:50
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 10:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:29:51
Query 'Data is required. Please provide.' answered with 'Start time unknown' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 16:02:12
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 16:00:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:00:46
User closed query 'Data entered is non-conformant.' Please correct.' (Site from System).	System	19 Nov 2020 15:15:51
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 15:15:51
User opened query 'Data entered is non-conformant.' Please correct.' (Site from System).	System	19 Nov 2020 15:14:11
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 15:14:11
User entered 'UN:UN' (non-conformant).	(b) (4), (b) (6)	19 Nov 2020 15:14:11
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 15:13:10
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User entered empty.	System	19 Nov 2020 16:00:46
User entered '16 Sep 2020 00:00'	System	19 Nov 2020 15:15:51
User entered '16 Sep 2020 UN:UN' (non-conformant).	System	19 Nov 2020 15:14:11
User entered empty.	System	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:29:56
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 15:13:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 15:13:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 15:13:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:50
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:29:59
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	19 Nov 2020 16:02:44
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	19 Nov 2020 16:02:44
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	19 Nov 2020 16:00:46
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 15:13:10
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 10:21:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:00
Query 'Data is required. Please provide.' answered with 'end time unknown' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 16:03:00
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 16:00:46
User closed query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	19 Nov 2020 16:00:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:00:46
User opened query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	19 Nov 2020 15:15:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Nov 2020 15:15:51
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 15:15:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Nov 2020 15:14:11
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 15:14:11
User entered 'UN:UN' (non-conformant).	(b) (4), (b) (6)	19 Nov 2020 15:14:11
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 15:13:10
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User entered empty.	System	19 Nov 2020 16:00:46
User entered '16 Sep 2020 00:00'	System	19 Nov 2020 15:15:51
User entered '16 Sep 2020 UN:UN' (non-conformant).	System	19 Nov 2020 15:14:11
User entered empty.	System	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:06
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:03:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 16:03:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:03:09
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:50
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:08
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:00:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 16:00:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:00:46
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:50
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:12
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:13
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:15
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:18
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:28
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:34
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:41
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:45
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:56
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:58
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:06
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:00:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 16:00:46
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:00:46
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:50
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:11
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:00:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 16:00:46
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:00:46
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:50
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:16
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:00:46
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 15:13:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 15:13:10
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 15:13:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:50
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 16:00:46
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:00:46
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Nov 2020 19:33:50
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:23
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:26
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	19 Nov 2020 16:02:44
Data Entry Error		
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:00:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 16:00:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:00:46
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:50
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:35
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:38
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User entered '0'	System	19 Nov 2020 16:00:46

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40
User entered '1'	System	18 Nov 2020 19:33:50

US3752162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:40

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Chest and respiratory tract injuries NEC, PT: Pulmonary contusion, LLT: Contusion pulmonary - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 17:53:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 17:53:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:31:59
Data point term sent to Coder	System	19 Nov 2020 17:53:10
User entered 'CONTUSED RIGHT LUNG(from MVA)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:24
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:27
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:30
User entered '16 Sep 2020'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:35
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Nov 2020 17:54:05
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:54:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Nov 2020 17:53:20
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 17:53:20
User entered '--:--' (non-conformant).	(b) (4), (b) (6)	19 Nov 2020 17:53:20
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 17:52:58
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User entered '16 Sep 2020 00:00'	System	19 Nov 2020 17:54:05
User entered '16 Sep 2020 --:--' (non-conformant).	System	19 Nov 2020 17:53:20
User entered empty.	System	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 15:56:15
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4)	21 Jan 2021 16:18:16
	(b) (4)	
DataPoint Un-verified.	Jamie Pettus (b) (4)	21 Jan 2021 16:17:35
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	21 Jan 2021 16:17:35
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 06:25:10
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Un-verified.	Jamie Pettus (b) (4)	21 Jan 2021 16:17:35
	(b) (4)	
User entered '26 Nov 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4)	21 Jan 2021 16:17:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:18:34
DataPoint Un-verified.	Jamie Pettus (b) (4)	21 Jan 2021 16:18:34
	(b) (4)	
User entered '08:00' reason for change: Data Entry Error	Jamie Pettus (b) (4)	21 Jan 2021 16:18:34
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 16:17:35
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:49
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User entered '26 Nov 2020 08:00'	System	21 Jan 2021 16:18:34
User entered empty.	System	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:58
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:01
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:05
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:08
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:11
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:16
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:20
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:27
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:22
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:33
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:38
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:42
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:48
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:02
User entered 'None (NONE)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:11
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 17:54:42
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:54:42
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 17:52:58
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:16
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:20
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Un-verified.	Jamie Pettus (b) (4)	21 Jan 2021 16:17:35
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jamie Pettus (b) (4)	21 Jan 2021 16:17:35
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	19 Nov 2020 17:52:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:33
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:38
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User entered '0'	System	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24
User entered '1'	System	19 Nov 2020 17:52:58

US3752162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:24

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod bite, LLT: Spider bite - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 15:19:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 15:19:59
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:57:34
Data point term sent to Coder	System	26 Mar 2021 18:41:14
Coding entries removed.	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 18:40:23
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 18:40:23
User entered 'SKIN LESIONS X2 TO RIGHT LOWER EXTREMITY STATUS POST POSSIBLE SPIDER BITES' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 18:40:23
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:28:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod bite, LLT: Insect bite NOS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 05:12:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 05:12:09
Data point term sent to Coder	System	01 Mar 2021 19:38:26
User entered 'INSECT BITES RIGHT LOWER EXTREMITIES'	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:37:45

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Yes (Y)'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
Signature has been broken.	Haylee Rowe (b) (4)	26 Mar 2021 18:40:23
	(b) (4)	
User entered '18 Nov 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4)	26 Mar 2021 18:40:23
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '04 Jan 2021'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 19:37:45

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
Signature has been broken.	Haylee Rowe (b) (4)	26 Mar 2021 18:40:23
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	26 Mar 2021 18:40:23
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
Signature has been broken.	Haylee Rowe (b) (4)	26 Mar 2021 18:40:23
	(b) (4)	
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4)	26 Mar 2021 18:40:23
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '14 Jan 2021'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 19:37:45

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
Signature has been broken.	Haylee Rowe (b) (4)	26 Mar 2021 18:40:23
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	26 Mar 2021 18:40:23
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'None (NONE)'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '1'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
Signature has been broken.	Haylee Rowe (b) (4)	26 Mar 2021 18:40:23
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Haylee Rowe (b) (4)	26 Mar 2021 18:40:23
Data Entry Error	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	01 Mar 2021 19:37:45
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Mar 2021 19:37:45

US3752162

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:26:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 19:37:45

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 18:49:28
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 18:49:28
	(b) (4)	
Data point term sent to Coder	System	26 Mar 2021 18:48:25
User entered 'DEPRESSION'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered '17 Mar 2021'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 18:48:02

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 18:48:02

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered 'None (NONE)'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered '1'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered 'Unknown (UNKNOWN)'	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:57:34
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	26 Mar 2021 18:48:02
	(b) (4)	

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 18:48:02

US3752162

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:26:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 18:48:02

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:26:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:39:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 02:18:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:37:07

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:54:51
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:40:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:40:19
Data point term sent to Coder	System	20 Aug 2020 16:38:47
User entered 'Tamsulosin'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:54:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:54:55
User entered 'Prostate enlargement'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:54:57
User entered '0.4'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:55:00
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:55:03
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:55:05
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:55:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:55:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:55:14
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:55:16
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:41:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:38:01
User entered 'un Feb 2020'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:55:18
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:55:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:55:24
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:55:26
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:38:01

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 10:57:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 10:57:14
Data point term sent to Coder	System	30 Oct 2020 16:39:24
User entered 'METHOCARBAMOL'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:22
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:24
User entered 'TREAT POST-OPERATIVE PAIN'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:27
User entered '750'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:31
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:35
User entered 'as needed (PRN)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:37
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:41
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:42
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:44
User entered '15 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:56:50
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:57:01
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:57:07
User entered '23 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:57:10
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User entered empty.	System	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User entered empty.	System	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:05
User entered empty.	System	30 Oct 2020 16:38:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 21:29:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:29:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:57:56
Data point term sent to Coder	System	06 Nov 2020 17:03:46
Coding entries removed.	(b) (4), (b) (6)	06 Nov 2020 17:03:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:09:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:09:18
Data point term sent to Coder	System	30 Oct 2020 16:40:25
User entered 'HYDROCODONE'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:57:57
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:57:59
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)	06 Nov 2020 20:36:37
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 'Please see AE. AE added today.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:03:45
User entered 'TREATMENT OF POST-OPERATIVE PAIN from laminectomy' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:03:34
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)	06 Nov 2020 15:36:01
User entered 'TREATMENT OF POST-OPERATIVE PAIN'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4)	24 Feb 2021 18:59:05
User closed query 'Source says 10mg--please update EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 18:59:02
Query 'Source says 10mg--please update EDC or clarify.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 16:30:10
User entered '10' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 16:30:01
User opened query 'Source says 10mg--please update EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	30 Nov 2020 21:23:28
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 21:22:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:08
User entered '7.5' reason for change: Data Entry Error	Lauren Evans (b) (4)	09 Nov 2020 20:32:03
User entered '10'	Amanda Horn (b) (4)	30 Oct 2020 16:39:37
	(b) (4)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:09
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:13
User entered 'as needed (PRN)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:16
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:20
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:24
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:28
User entered '15 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:31
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:38
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:41
User entered '23 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:58:48
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered empty.	System	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered empty.	System	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered empty.	System	30 Oct 2020 16:39:37

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 17:47:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 17:47:33
Data point term sent to Coder	System	08 Nov 2020 17:46:40
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 17:46:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;DIPHENHYDRAMINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:30:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:30:22
Data point term sent to Coder	System	06 Nov 2020 17:09:56
Coding entries removed.	(b) (4), (b) (6)	06 Nov 2020 17:09:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 12:58:17

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[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 Coding entries removed.	Coder Import (b) (4) (b) (4) System Amanda Horn (b) (4) (b) (4)	05 Nov 2020 12:58:17 05 Nov 2020 00:16:37 05 Nov 2020 00:15:45
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:15:45
User entered 'ACETAMINOPHEN/DIPHENHYDRAMINE' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:15:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:28:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	31 Oct 2020 11:28:15 30 Oct 2020 16:41:25
User entered 'ACETAMINOPHEN/BENADRYL'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:28
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:30
User closed query 'Per CDM: Please clarify if Insomnia is related to COVID-19 or MH. Please update MH applicable.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:28:31
Query 'Per CDM: Please clarify if Insomnia is related to COVID-19 or MH. Please update MH applicable.' answered with 'SLEEP AID TAKEN TO TREAT INTERRUPTED SLEEP DUE TO SYMPTOMS OF COVID-19 INFECTION' (Site from DM).	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 17:46:17
User entered 'TREATMENT OF SYMPTOMS RELATED COVID-19/SLEEP AID' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 17:46:06
User opened query 'Per CDM: Please clarify if Insomnia is related to COVID-19 or MH. Please update MH applicable.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:41:27
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (SLEEP AID). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:39:52
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (SLEEP AID). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:10:00
User entered 'TREATMENT OF SYMPTOMS RELATED COVID-19/SLEEP AID for insomnia' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:09:53
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (SLEEP AID). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:35:26

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'TREATMENT OF SYMPTOMS RELATED COVID-19/SLEEP AID' reason for change: Data Entry Error	Amanda Horn (b) (4)	05 Nov 2020 00:15:45
User entered 'TREATMENT OF PAIN, FEVER, SLEEP AID'	Amanda Horn (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:33
User entered '1000/50'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:35
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:43
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:45
User entered 'as needed (PRN)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:49
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:52
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:58
User entered '20 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:04
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:09
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:12
User entered '20 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:14
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User entered empty.	System	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User entered empty.	System	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:10
User entered empty.	System	30 Oct 2020 16:40:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:10:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:10:31
Data point term sent to Coder	System	05 Nov 2020 00:09:34
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:09:33
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:09:33
User entered 'ACETAMINOPHEN' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:09:33
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)	30 Oct 2020 16:56:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:56:55
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)	30 Oct 2020 16:41:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:41:56
Data point term sent to Coder	System	30 Oct 2020 16:41:26
User entered 'TYLENOL'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:39
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:41
User entered 'TREATMENT OF SYMPTOMS RELATED TO COVID-19' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:09:33
User entered 'FEVER, PAIN'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:44
User entered '1000'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:47
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:49
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:51
User entered 'as needed (PRN)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:00:56
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:00
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:03
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:06
User entered '17 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:09
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:11
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:16:32
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:14
User entered '31 Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:16:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:16
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User entered empty.	System	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User entered empty.	System	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:12
User entered empty.	System	30 Oct 2020 16:41:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:02:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:07:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:07:23
Data point term sent to Coder	System	06 Nov 2020 17:10:57
Data point term sent to Coder	System	06 Nov 2020 17:09:51
Coding entries removed.	(b) (4), (b) (6)	06 Nov 2020 17:09:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:26:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:26:56
Data point term sent to Coder	System	30 Oct 2020 16:42:27
User entered 'ASPIRIN'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:02:13
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:02:26
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:46:53
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:10:56
User entered 'PROPHYLAXIS FOR DEEP VENOUS THROMBOSIS following laminectomy' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:10:50
User entered 'Prophylaxis for deep venous thrombosis' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:09:19
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:35:44
User entered 'REDUCE RISK OF BLOOD CLOTS'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:02:58
User entered '81'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:00
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:02
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:08
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:09
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:13
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:24:51
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:20
User entered '20 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:22
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:24
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:27
User entered '23 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:29
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User entered '1'	System	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User entered '1'	System	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:14
User entered '804 (804)'	System	30 Oct 2020 16:42:13

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY [ZINC ACETATE;ZINC GLUCONATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:14:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:14:20
Data point term sent to Coder	System	02 Nov 2020 18:21:55
User closed query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	02 Nov 2020 18:21:23
Query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'UPDATED' (Site from System).	Amanda Horn (b) (4) (b) (4)	02 Nov 2020 18:21:23
User entered 'ZICAM COLD REMEDY/ ZINCUM ACETICUM/ZINCUM GLUCONICUM' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	02 Nov 2020 18:21:15
User opened query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4) (b) (4)	01 Nov 2020 12:56:45
Data point term sent to Coder	System	30 Oct 2020 16:43:28
User entered 'ZICAM'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:03:59
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:02
User entered 'SHORTEN DURATION OF COVID SYMPTOMS'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:06
User entered '1' reason for change: Data Entry Error	Amanda Horn (b) (4)	04 Nov 2020 23:47:57
User entered '3'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:09
User entered 'tablet (TABLET)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:19
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:29
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:34
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:40
User entered '22 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:45
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:53:41
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'data changed to reflect information in AE' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:33:24
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:33:10
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:33:10
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:34:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:04:49
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Un-verified.	(b) (4)	11 Jan 2021 20:33:10
User entered '05 Nov 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4)	11 Jan 2021 20:33:10
DataPoint Verified.	(b) (4)	10 Nov 2020 17:04:52
User entered empty.	Amanda Horn (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:04:53
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 16:46:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 16:46:59
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:59
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 16:43:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User entered '1'	System	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User entered '1'	System	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:16
User entered '804 (804)'	System	30 Oct 2020 16:43:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:05:26
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)	31 Oct 2020 01:02:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 01:02:09
Data point term sent to Coder	System	30 Oct 2020 16:44:29
User entered 'PEPCID'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:05:29
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:05:32
User entered 'SHORTEN DURATION/DECREASE SEVERITY OF SYMPTOMS RELATED TO COVID-19'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:05:38
User entered '20'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:05:41
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:05:44
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:05:47
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:05:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:06:00
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:06:03
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:06:09
User entered '20 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:06:16
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:53:45
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'data changed to reflect AE' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:34:40
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:34:30
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:34:30
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:34:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:06:23
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Un-verified.	(b) (4)	11 Jan 2021 20:34:30
User entered '05 Nov 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4)	11 Jan 2021 20:34:30
DataPoint Verified.	(b) (4)	10 Nov 2020 17:06:29
User entered empty.	Amanda Horn (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:06:31
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User entered '1'	System	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User entered '1'	System	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:18
User entered '804 (804)'	System	30 Oct 2020 16:44:08

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 00:45:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 00:45:05
Data point term sent to Coder	System	30 Oct 2020 16:45:31
User entered 'VITAMIN C'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:26
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:28
User entered 'TREATMENT OF SYMPTOMS RELATED TO COVID-19'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:30
User entered '1000'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:33
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:37
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:38
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:41
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:43
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:44
User entered '28 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:46
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:53:49
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'data changed to reflect AE' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:35:47
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:35:19
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:35:19
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:35:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:07:47
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	11 Jan 2021 20:35:30
User entered '05 Nov 2020' reason for change: Data Entry Error	System	11 Jan 2021 20:35:30
User opened query 'Future date has been entered. Please correct.' (Site from System).	Jamie Pettus (b) (4)	11 Jan 2021 20:35:30
DataPoint Un-verified.	(b) (4)	11 Jan 2021 20:35:19
User entered '05 Nov 2021' reason for change: Data Entry Error	Jamie Pettus (b) (4)	11 Jan 2021 20:35:19
DataPoint Verified.	(b) (4)	11 Jan 2021 20:35:19
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:07:50
	Amanda Horn (b) (4)	30 Oct 2020 16:45:11
	(b) (4)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:51
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User entered '1'	System	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User entered '1'	System	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User entered '804 (804)'	System	30 Oct 2020 16:45:11

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 04:44:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 04:44:53
Data point term sent to Coder	System	05 Nov 2020 00:17:38
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:17:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 00:44:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 00:44:04
Data point term sent to Coder	System	30 Oct 2020 16:47:34
User entered 'VITAMIN D'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:08
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:10
User entered 'TREATMENT OF SYMPTOMS RELATED TO COVID-19' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 00:17:25
User entered 'TREATMENT OF SYMPTOMS OF COVID-19'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:12
User entered '1000'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:14
User entered 'IU (IU)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:16
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:19
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:25
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:30
User entered '28 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:35
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:53:53
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'data changed per AE' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:36:45
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:36:09
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 20:36:09
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:35:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:37
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Un-verified.	(b) (4)	11 Jan 2021 20:36:09
User entered '05 Nov 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4)	11 Jan 2021 20:36:09
DataPoint Verified.	(b) (4)	10 Nov 2020 17:08:38
User entered empty.	Amanda Horn (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:08:40
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User entered '1'	System	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User entered '1'	System	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:26
User entered '804 (804)'	System	30 Oct 2020 16:46:41

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: KEFLEX [CEFALOXIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 05:32:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:32:33
Data point term sent to Coder	System	09 Nov 2020 20:35:02
User entered 'Keflex'	Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'POST OP MEDICATION AFTER hemiLAMINECTOMY' reason for change: Data Entry Error	(b) (4)	
	Lauren Evans (b) (4)	09 Nov 2020 20:34:59
User entered 'post op medication after laminectomy'	Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '500'	(b) (4) Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'mg (mg)'	(b) (4) Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	09 Nov 2020 20:34:23
	Lauren Evans (b) (4)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'twice daily (BID)'	(b) (4) Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	09 Nov 2020 20:34:23
	Lauren Evans (b) (4)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Oral (ORAL)'	(b) (4) Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	09 Nov 2020 20:34:23
	Lauren Evans (b) (4)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '15 Oct 2020'	(b) (4)	
	Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '17 Oct 2020'	(b) (4)	
	Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User entered '2'	System	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User entered '1'	System	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:30
User entered '804 (804)'	System	09 Nov 2020 20:34:23

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 20:37:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 20:37:37
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 20:37:04
User entered 'Claritin'	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM). Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'seasonal allergies added to medical history' (Site from DM). User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM). User entered 'seasonal allergies'	(b) (4) (b) (4), (b) (6) Jamie Pettus (b) (4) (b) (4) (b) (4), (b) (6) Lauren Evans (b) (4)	13 Jan 2021 18:54:10 11 Jan 2021 21:09:29 31 Dec 2020 07:36:48 09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '10'	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'mg (mg)'	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'once daily (QD)'	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '15 Oct 2020'	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Yes (Y)'	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 20:36:20

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 20:42:36
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	09 Nov 2020 20:42:36
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 20:41:14
User entered 'Robaxin'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'post op medication after hemilaminectomy'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '750'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'mg (mg)'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'three times daily (TID)'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '15 Oct 2020'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Yes (Y)'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 20:40:15

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 05:26:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:26:28
Data point term sent to Coder	System	09 Nov 2020 20:42:16
User entered 'Ibuprofen'	Lauren Evans (b) (4) (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'post op pain after hemilaminectomy'	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '800'	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'mg (mg)'	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'as needed (PRN)'	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '15 Oct 2020'	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Yes (Y)'	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:41:31

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Nov 2020 03:54:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 03:54:42
Data point term sent to Coder	System	09 Nov 2020 20:44:20
User entered 'docusate sodium'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Yes (Y)'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'constipation prophylaxis after surgery'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '100'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'mg (mg)'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'twice daily (BID)'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '15 Oct 2020'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'Yes (Y)'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 20:43:36

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 10:35:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 10:35:12
Data point term sent to Coder Coding entries removed.	System Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:37:26 01 Mar 2021 19:36:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:22:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:22:31
Data point term sent to Coder User entered 'Clindamycin'	System (b) (4), (b) (6)	18 Jan 2021 21:09:55 18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
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 appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:30:14
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
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 appropriate. ' answered with 'AE entered' (Site from DM).	(b) (4)	
User entered 'INSECT BITeS RIGHT LOWER EXTREMITIES' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Mar 2021 19:38:20
User entered 'insect bits right lower extremities' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Mar 2021 19:36:39
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 appropriate. ' (Site from DM).	(b) (4)	01 Mar 2021 19:36:26
User entered 'Skin/lesion x2 to RLE status post possible spider bites'	(b) (4), (b) (6)	11 Feb 2021 19:22:41
	(b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '300'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User entered '3'	System	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User entered '1'	System	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:34
User entered '804 (804)'	System	18 Jan 2021 21:09:05

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:24:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:24:49
Data point term sent to Coder	System	24 Mar 2021 16:58:33
User entered 'wellburtin'	(b) (4), (b) (6)	24 Mar 2021 16:57:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'No (N)'	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'depression'	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '150'	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'mg (mg)'	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 16:57:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'once daily (QD)'	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered empty.	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Oral (ORAL)'	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 16:57:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '24 Mar 2021'	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered '0'	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'Yes (Y)'	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered empty.	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:58
User entered 'No (N)'	(b) (4)	24 Mar 2021 16:57:57
	(b) (4), (b) (6)	

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 16:57:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 16:57:57

US3752162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:26:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Mar 2021 16:57:57

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:26:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:39:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:29:21
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:47:07

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:26:31

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:30:42
User closed query 'Per DM CLR: Noted Indication=Medical History. Please review the Date of this procedure/Surgery, as this is after first dose of study vaccination. Please review and verify a logical corresponding Medical History is recorded, and procedure start date is within the timeframe of the Med History. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:52:23
Query 'Per DM CLR: Noted Indication=Medical History. Please review the Date of this procedure/Surgery, as this is after first dose of study vaccination. Please review and verify a logical corresponding Medical History is recorded, and procedure start date is within the timeframe of the Med History. Otherwise, provide clarification. ' answered with 'Added AE regarding procedure.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:55:54
User opened query 'Per DM CLR: Noted Indication=Medical History. Please review the Date of this procedure/Surgery, as this is after first dose of study vaccination. Please review and verify a logical corresponding Medical History is recorded, and procedure start date is within the timeframe of the Med History. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:21:55
User entered '15 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:48:16

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:26:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:30:44
User entered 'L5 S1 DISCECTOMY WITH RIGHT LATERAL HEMILAMINECTOMY'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:48:16

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:32:01
User entered 'Medical History (MH)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 16:13:37
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:52:08
User closed query 'Per CDM: Please mention in the query response the Medical History where this procedure was performed for.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 05:02:32
Query 'Per CDM: Please mention in the query response the Medical History where this procedure was performed for.' answered with 'low back pain' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:28:54
User opened query 'Per CDM: Please mention in the query response the Medical History where this procedure was performed for.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:58:09
User entered 'Medical History (MH)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:48:16

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:26:31

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:32:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 16:48:16

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:26:31

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '30 Sep 2020'	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 17:51:08
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:26:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'LUMBAR F/E X-RAY'	Haylee Rowe (b) (4)	10 Nov 2020 17:51:08

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Diagnostic (DIAGNOSTIC)'	Haylee Rowe (b) (4)	10 Nov 2020 17:51:08

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:26:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	10 Nov 2020 17:51:08
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 12 Aug 2021 13:26:31

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered '02 Sep 2020'	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 17:51:44
	(b) (4)	

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 12 Aug 2021 13:26:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'MRI LUMBAR W/O CONTRAST'	Haylee Rowe (b) (4)	10 Nov 2020 17:51:44

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 12 Aug 2021 13:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered 'Diagnostic (DIAGNOSTIC)'	Haylee Rowe	10 Nov 2020 17:51:44

US3752162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 12 Aug 2021 13:26:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	10 Nov 2020 17:51:44
	(b) (4)	

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'Visit 3 Day 57 (VISIT3)'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'l'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'l'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'I'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

Central Laboratory - Nasopharyngeal Swab

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'l'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '21 Oct 2020'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'l'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'I'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	23 Feb 2021 21:34:31
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'I'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered 'l'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:26:31

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 21:30:16
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:28:49
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Feb 2021 21:34:31

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered		
'USA-US113-2020-MRNA-1273-P301000004'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'Priyantha'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'Wijewardane'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 13:53:20
User entered 'US'	System	02 Nov 2020 14:17:00

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
User entered '2'	System	09 Nov 2020 13:53:28
User entered '1'	System	02 Nov 2020 14:17:00

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered		
'USA-US113-2020-MRNA-1273-P301000004'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'Priyantha'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'Wijewardane'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 13:53:20
User entered 'US'	System	02 Nov 2020 14:17:00

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
User entered '2'	System	09 Nov 2020 13:53:28
User entered '1'	System	02 Nov 2020 14:17:00

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:26:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
User entered '02/Nov/2020 14:16'	System	02 Nov 2020 14:17:00

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:26:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 13:53:20
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 14:17:00

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered		
'USA-US113-2020-MRNA-1273-P301000004'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'No (N)'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'Priyantha'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:16:53
User entered 'Wijewardane'	System	02 Nov 2020 14:16:34

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 13:53:20
User entered 'US'	System	02 Nov 2020 14:17:00

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
User entered '2'	System	09 Nov 2020 13:53:28
User entered '1'	System	02 Nov 2020 14:17:00

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:26:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:12
User entered '09/Nov/2020 08:53'	System	09 Nov 2020 13:53:28

US3752162

Folder: SAE USA-US113-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:26:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:37:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:17:12
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 13:53:28