

US3752025 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:41:55

All time stamps listed in this document are displayed in GMT

US3752025

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 18:02:40

Generated On: 10 Jun 2021 09:41:55

[Participant ID](#)

US3752025

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

US3752025

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

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

Visit date (dd MMM yyyy)	10 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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US3752025

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input checked="" type="radio"/> Male <input 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

US3752025

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input 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

US3752025

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3752025

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Were any significant conditions reported?

Yes ☒

No ☐

US3752025

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	HYPERCHOLESTEROLEMIA
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)	_____

US3752025

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	DIABETES MELLITUS TYPE II
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)	_____

US3752025

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	GERD/REFLUX
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3752025

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	SURGICAL STERILIZATION/HYSTERECTOM Y
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

US3752025

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	ANXIETY
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)	

US3752025

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	BACK SURGERY (ASSOCIATED CONDITION UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

US3752025

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	BACK SURGERY (ASSOCIATED CONDITION UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	CHOLECYSTECTOMY (ASSOCIATED CONDITION UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

US3752025

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	AORTIC ANEURYSM
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1989
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	CHOLECYSTECTOMY
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 (21)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	LAPAROSCOPIC HYSTERECTOMY FOR ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	TUBAL LIGATION
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)	

US3752025

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	WISDOM TOOTH EXTRACTION
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)	

US3752025

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	RIGHT BREAST BIOPSIES X 4
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)	

US3752025

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	TOBACCO ABUSE
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)	

US3752025

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	CHRONIC BACK PAIN
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)	

US3752025

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Condition	LEFT RENAL MASS
Start date (dd MMM yyyy)	20 JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3752025

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:58 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:58
Height (<i>xxx.x</i>)	165.0 cm
Weight (<i>xxx.x</i>)	244.5 lb
BMI (<i>xxx.x</i>)	40.82144 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)	

US3752025

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Date of assessment (dd MMM yyyy) 10 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1989

Date of surgery unknown False

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

Date of last menstruation unknown False

US3752025

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

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 DISABLED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:02:50

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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	True
Specify	RESIDES IN DUPLEX APARTMENT

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

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

What was the participant's randomization number? 143502

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

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 18:02:50

Generated On: 10 Jun 2021 09:41:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:58
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)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	078 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 18:02:50

Generated On: 10 Jun 2021 09:41:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:00
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	078 mmHg
Diastolic Blood Pressure units	MMHG

US3752025

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

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.

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:27 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 12:27

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

US3752025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 AUG 2020
Collection time (00:00-23:59)	11:04 (24 HR)
Collection date and time (derived)	10 AUG 2020 11:04

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:07	10 AUG 2020 11:07
Nasopharyngeal Swab 2	No		

US3752025

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 13:07

PC Open Date & Time

10 AUG 2020 12:47

PC Close Date & Time

10 AUG 2020 15:17

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	10 AUG 2020 19:54
PC Open Date & Time	10 AUG 2020 16:12
PC Close Date & Time	11 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 12:35

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 12:15

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:54

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 13:11

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

15 AUG 2020 13:08

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 12:36

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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

10 AUG 2020 13:07

PC Open Date & Time

10 AUG 2020 12:47

PC Close Date & Time

10 AUG 2020 15:17

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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

10 AUG 2020 19:54

PC Open Date & Time

10 AUG 2020 16:12

PC Close Date & Time

11 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

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

11 AUG 2020 12:36

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

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

12 AUG 2020 12:16

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

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

13 AUG 2020 12:54

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

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

14 AUG 2020 13:11

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 13:08

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:37

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 12:47

PC Close Date & Time

10 AUG 2020 15:17

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 19:55
PC Open Date & Time	10 AUG 2020 16:12
PC Close Date & Time	11 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

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 ☒

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:16
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:55
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 13:11
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 13:09
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

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)

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US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:37
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3752025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

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)	21 SEP 2020
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:21
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:35
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	100 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)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3752025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 10:19 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 10:19

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

US3752025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

09:42 (24 HR)

Collection date and time (derived)

21 SEP 2020 09:42

US3752025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:39	21 SEP 2020 09:39
Nasopharyngeal Swab 2	No		

US3752025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

99.0 °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 21 SEP 2020 10:40

PC Open Date & Time 21 SEP 2020 10:39

PC Close Date & Time 21 SEP 2020 13:09

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	21 SEP 2020 20:07
PC Open Date & Time	21 SEP 2020 14:04
PC Close Date & Time	22 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 13:24

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 20:16

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 12:36

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

25 SEP 2020 18:37

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 12:15

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 10:41

PC Open Date & Time

21 SEP 2020 10:39

PC Close Date & Time

21 SEP 2020 13:09

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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

21 SEP 2020 20:08

PC Open Date & Time

21 SEP 2020 14:04

PC Close Date & Time

22 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

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

22 SEP 2020 13:24

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

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

23 SEP 2020 20:17

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

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

24 SEP 2020 12:36

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

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

25 SEP 2020 18:37

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

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

26 SEP 2020 12:01

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 12:16

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 10:42
PC Open Date & Time	21 SEP 2020 10:39
PC Close Date & Time	21 SEP 2020 13:09

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 20:09
PC Open Date & Time	21 SEP 2020 14:04
PC Close Date & Time	22 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

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 ☒

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 13:25
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 20:17
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

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 ☒

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

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 ☒

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:38
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

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 ☒

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 12:01
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:16
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3752025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 10:10
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 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)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3752025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

19 OCT 2020 10:15

US3752025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:50

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT	DAY 99
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"/>

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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°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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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="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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 138

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	27 DEC 2020 23:59
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US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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="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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 166

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 FEB 2021 09:53:00
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 00:02:03

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 13:00:51
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

07 MAR 2021 08:42:49

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

12 MAR 2021 12:50:03

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 222

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 <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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	29 AUG 2021 23:59
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US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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°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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	17 OCT 2021 23:59
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US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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°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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 <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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	26 DEC 2021 23:59
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US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
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Patient Cloud Close Date & Time	30 JAN 2022 23:59
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US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
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Patient Cloud Close Date & Time	27 FEB 2022 23:59
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US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 656

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

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

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

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

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

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

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
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Patient Cloud Close Date & Time	31 JUL 2022 23:59
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US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 726

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

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

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

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

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

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

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

DAY 789

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

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

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

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

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

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

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 ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 OCT 2022 00:01
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Patient Cloud Close Date & Time	16 OCT 2022 23:59
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US3752025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:41:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		07 MAR 2021 08:42:15

US3752025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:02:49

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

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

Visit date (dd MMM yyyy)	09 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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US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 16:33:33

Generated On: 10 Jun 2021 09:41:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 MAR 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 11:20
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3752025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	11:30 (24 HR)
Collection date and time (derived)	09 MAR 2021 11:30

US3752025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 21 Apr 2021 00:12:45

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 21 Apr 2021 00:12:45

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 18:02:42

Generated On: 10 Jun 2021 09:41:55

Date of Contact	9 OCT 2020
Time of Contact	13:00
Date and Time of Contact (derived)	9 OCT 2020 13:00
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>

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 OCT 2020
------	-------------

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

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

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

Temperature	97.9 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 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

	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"/>

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 OCT 2020
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

	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"/>

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 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 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

	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"/>

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 18:02:42

Generated On: 10 Jun 2021 09:41:55

Date of Visit	9 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	9 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Feb 2021 18:02:42

Generated On: 10 Jun 2021 09:41:55

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 18:02:42

Generated On: 10 Jun 2021 09:41:55

Date of Contact	12 NOV 2020
Time of Contact	11:30
Date and Time of Contact (derived)	12 NOV 2020 11:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	8 NOV 2020
------	------------

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

O2 Saturation	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 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 NOV 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	98.3 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input 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 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 12 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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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Form: Symptom Log (7)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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 (7)

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	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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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Form: Symptom Log (7)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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)

Data signed: (b) (4) 23 Mar 2021 23:09:26

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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)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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 (8)

Data signed: (b) (4) 23 Mar 2021 23:09:26

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	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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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Form: Symptom Log (8)

Data signed: (b) (4) 23 Mar 2021 23:09:26

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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 (9)

Data signed: (b) (4) 23 Mar 2021 23:09:26

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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 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 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 (9)

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	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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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Form: Symptom Log (9)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.7 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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	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input 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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Form: Symptom Log (10)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 (11)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 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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	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input 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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Data signed: (b) (4) 23 Mar 2021 23:09:26

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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 (12)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 12 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 NOV 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	96.7 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 (12)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input 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 (12)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input 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 12 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 NOV 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	97.7 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 (13)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input 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 (13)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input 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 12 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.0 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 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 (14)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input 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 (14)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input 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 (15)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 NOV 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	97.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input 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 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input 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 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		438 of 4640
EAB) (1725)		

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input 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 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	24 NOV 2020
------	-------------

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

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

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

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input 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 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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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input 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 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
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 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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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 12 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.0 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 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 (19)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 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 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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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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 12 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input checked="" type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 23 Mar 2021 23:09:26

Generated On: 10 Jun 2021 09:41:55

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"/>

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 18:02:42

Generated On: 10 Jun 2021 09:41:55

Date of Visit 10 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Date of Test 10 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒
No ☐

If yes, provide lab information below

Lab/ Institution Test Performed BHMC NORTH LITTLE ROCK
3333 SPRINGHILL DR.
NORTH LITTLE ROCK AR 72114

CLIA Certified? Yes ☒
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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 10 NOV 2020

End Date 17 NOV 2020

Oxygen Saturation 92 %

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 _____

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

10 NOV 2020

End Date

13 NOV 2020

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	Yes	16 NOV 2020
Day 9	Yes	18 NOV 2020
Day 14	Yes	23 NOV 2020
Day 21	Yes	30 NOV 2020
Day 28	Yes	8 DEC 2020

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:30 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 15:30
Height (<i>xxx.x</i>)	065.0 in
Weight (<i>xxx.x</i>)	239.9 lb
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	109 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>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 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: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

9 OCT 2020

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

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) _____

Height (xxx.x) _____

Weight (xxx.x) _____

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) _____

US3752025

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

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.

US3752025

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 18:02:44

Generated On: 10 Jun 2021 09:41:55

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

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

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

Folder OID	
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US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

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.

US3752025

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:41:55

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:02:42

Generated On: 10 Jun 2021 09:41:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 DEC 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	8 DEC 2020 10:10
Height (xxx.x)	65.0 in
Weight (xxx.x)	249.9 lb
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:02:42

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 DEC 2020

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

US3752025

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 12 Feb 2021 18:02:42

Generated On: 10 Jun 2021 09:41:55

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 DEC 2020

US3752025

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

Form: Visit Date

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

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

Visit date (dd MMM yyyy)	12 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3752025

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 FEB 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>)	12 FEB 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

US3752025

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Height	165.1 cm
Weight	110.7 kg
BMI (xxx.x)	40.61192

US3752025

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Height	165.1 cm
Weight	110.7 kg
BMI (xxx.x)	40.61192
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)	12 FEB 2021
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 14:35
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3752025

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Height	165.1 cm
Weight	110.7 kg
BMI (xxx.x)	40.61192
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)	12 FEB 2021
Time of assessment (00:00-23:59)	15:54 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 15:54
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3752025

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

Form: Physical Examination

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 FEB 2021

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

US3752025

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

Form: Exposure

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

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) 12 FEB 2021

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

Treatment Date and Time (derived) 12 FEB 2021 15:24

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

US3752025

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

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

Collection date (dd MMM yyyy)	12 FEB 2021
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Collection time (00:00-23:59)	15:03 (24 HR)
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Collection date and time (derived)	12 FEB 2021 15:03
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US3752025

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 FEB 2021
Collection time (00:00 - 23:59)	14:39
Collection Date and Time (derived)	12 FEB 2021 14:39

US3752025

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

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:21:28

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3752025

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	OLD29

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

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)	09 MAR 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 11:20
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

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)	09 MAR 2021
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 12:36
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)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3752025

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3752025

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

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) 09 MAR 2021

What was the treatment time? (00:00-23:59) 12:06 (24 HR)

Treatment Date and Time (derived) 09 MAR 2021 12:06

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

US3752025

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 16:12:19

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752025

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 17 Mar 2021 20:25:12

Generated On: 10 Jun 2021 09:41:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 13:38:56

Generated On: 10 Jun 2021 09:41:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 13:38:56

Generated On: 10 Jun 2021 09:41:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 APR 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	07 APR 2021 11:05
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 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)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752025

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 13:38:56

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 APR 2021

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

US3752025

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 13:38:56

Generated On: 10 Jun 2021 09:41:55

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

Collection date (dd MMM yyyy)	07 APR 2021
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Collection time (00:00-23:59)	11:11 (24 HR)
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Collection date and time (derived)	07 APR 2021 11:11
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US3752025

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 18:02:40

Generated On: 10 Jun 2021 09:41:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

AEID	
Adverse event	COUGH
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)	2 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)	11 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

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)	_____

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

AEID

Adverse event

NON-CARDIAC CHEST
TIGHTNESS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

2 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

9 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 ☐

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EAB) (1725)

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

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)	

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

AEID	USA-US113-2020-MRNA-1273-P30 1000013
Adverse event	HYPOTENSION
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)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 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 type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

PATIENT CONTACTED STUDY
SITE TODAY, 12 NOV 2020, AND
REPORTED THAT SHE HAS
BEEN IN THE HOSPITAL SINCE
10 NOV 2020.

SUBJECT'S BLOOD PRESSURE
WAS MEASURED AT 89/66 IN
THE EMERGENCY ROOM. UPON
DISCHARGE ON 13NOV2020 BP
WAS 114/79

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

AEID	USA-US113-2020-MRNA-1273-P30 1000013
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)	08 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	THE SUBJECT WAS ADMITTED TO INPATIENT FACILITY 10NOV2020 AND HAS NOT YET BEEN DISCHARGED.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

AEID	
Adverse event	WORSENING INTRACTABLE HEADACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	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 (6)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

AEID	USA-US113-2021-MRNA-1273-P30 1000005
Adverse event	CLEAR CELL RENAL CARCINOMA
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)	22 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	23 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

MEDICAL HISTORY INCLUDES
LEFT RENAL MASS WITH
START DATE 20JUL2020.
SCHEDULED INPATIENT
PROCEDURE WITH
PATHOLOGY INDICATING
CLEAR CELL RENAL
CARCINOMA. FOLLOW UP
WITH UROLOGY SCHEDULED
FOR 09FEB2021. NO COVID
TESTING DONE DURING THIS
ADMISSION.

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

AEID

Adverse event

POST-PROCEDURE PAIN
PARTIAL (NEPHRECTOMY)

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)

22 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

2 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SAW PCP AND GOT RAMAPRIL
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 (9)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

AEID

Adverse event

BILATERAL LOWER LUNG
RHONCHI

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)

09 MAR 2021

Start time (00:00-23:59)

00:00 (24 HR)

AE start date and time (derived)

09 MAR 2021 00:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 APR 2021

End time (00:00-23:59)

00:00 (24 HR)

AE End Date and Time (derived)

07 APR 2021 00:00

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 (9)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

AEID	
Adverse event	INCREASED PAIN IN RIGHT KNEE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 APR 2021
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 (10)

Data signed: (b) (4) 23 Apr 2021 23:36:00

Generated On: 10 Jun 2021 09:41:55

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 18:02:42

Generated On: 10 Jun 2021 09:41:55

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication LEVEMIR

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 26

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) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	2 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication PROTONIX (PANTOPRAZOLE)

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR SEASONAL
INFLUENZA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 SEP 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 (7)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication HUMALOG KWIK PEN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 12

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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) UN NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES II

Dose per administration VARIES

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify CONTINUOUS PUMP WITH MEALTIME BOLUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication HYPOTENSION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication HYPOTENSION

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication CHANTIX

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 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) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication ALBUTEROL
90MCG/ACTUATION

Prophylaxis Yes ☐
No ☒

Indication ASTHMA/COPD

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication SYMBICORT
160-4.5MCG/ACTUATION

Prophylaxis Yes ☐
No ☒

Indication ASTHMA/COPD

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication CHOLECALCIFEROL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC BACK PAIN

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication SLEEP APNEA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input 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 (17)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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

PER HOUR

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 25

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

If dose unit is Other, specify MCG

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 HOURLY AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

THREE TIMES DAILY AS
NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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

THREE TIMES DAILY AS
NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication INSULIN [REGULAR]

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES MELLITUS

Dose per administration 0-14

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

If dose unit is Other, specify UNITS

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 FOUR TIMES PER DAY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 checked="" type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication 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

EVERY 6 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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

EVERY 6 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication 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 ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 440

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (29)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication VERAPAMIL

Prophylaxis Yes ☐
No ☒

Indication INTRACTABLE HEADACHE

Dose per administration 120

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 (29)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication METOCLOPRAMIDE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF NAUSEA
RELATED TO ANESTHESIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 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)		22 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication MIDAZOLAM

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF ANXIETY
RELATED TO PROCEDURE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 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)		22 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication ONDANSETRON HCL

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF ANESTHESIA
RELATED NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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)		22 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POST PROCEDURE PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 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) 23 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POST PROCEDURAL PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 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)		02 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication RAMAPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication MEDICAL MARIJUANA

Prophylaxis Yes ☒
No ☐

Indication CHRONIC PAIN PREVENTION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 (36)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		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 (37)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication CBD HARD CANDY EDIBLES

Prophylaxis Yes ☒
No ☐

Indication CHRONIC PAIN PREVENTION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication INSULIN, REGULAR

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES MELLITUS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 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) 23 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication 0.99% NACL

Prophylaxis Yes ☐
No ☒

Indication PREVENTION OF FLUID
IMBALANCE

Dose per administration 100

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify CONTINUOUS INFUSION

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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)		23 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST PROCEDURE PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 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) 22 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST PROCEDURE PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 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)		02 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
CONSTIPATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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 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)	02 FEB 2021	
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 (43)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☒
No ☐

Indication PAIN PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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) 22 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication KETORLAC

Prophylaxis Yes ☒
No ☐

Indication PAIN PREVENTION

Dose per administration 15

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 (44)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 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)		22 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication INCREASED PAIN IN RIGHT
KNEE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	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)		31 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"/>

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE ARTHROSCOPY
PAIN MANAGEMENT

Dose per administration 15

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 (46)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE ARTHROSCOPY
PAIN MANAGEMENT

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication ONDANSETRON HCL

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PREVENTION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		23 APR 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication CEFAZOLIN IN STERILE WATER

Prophylaxis Yes ☒
No ☐

Indication INFECTION PREVENTION

Dose per administration 2/20

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

If dose unit is Other, specify G/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication VITAMIN D3
(CHOLECALCIFEROL)

Prophylaxis Yes ☐
No ☒

Indication BONE HEALTH

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication NORCO
(HYDROCODONE-ACETAMINOPHEN)

Prophylaxis Yes ☐
No ☒

Indication POST-PROCEDURE PAIN

Dose per administration 10-325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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 (51)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Name of Medication METOCLOPRAMIDE HCL

Prophylaxis Yes ☒
No ☐

Indication PRE/POST ANESTHESIA
NAUSEA PREVENTION

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 (52)

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 18:02:42

Generated On: 10 Jun 2021 09:41:55

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Apr 2021 23:36:01

Generated On: 10 Jun 2021 09:41:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 NOV 2020	CHEST XRAY 1 VIEW PORTABLE AP	Adverse Event	
10 NOV 2020	CT HEAD WITHOUT CONTRAST	Adverse Event	
21 OCT 2020	CT CHEST WITHOUT CONTRAST	Diagnostic	
21 OCT 2020	MYOCARDIAL PERFUSION/PHARMACOLOGIC STRESS TEST	Diagnostic	
22 JAN 2021	ROBOTIC ASSISTED LAPAROSCOPIC LEFT RETROPERITONEAL PARTIAL NEPHRECTOMY	Medical History	
06 APR 2021	MRI OF RIGHT KNEE	Adverse Event	
23 APR 2021	ATHROSCOPY OF RIGHT KNEE	Adverse Event	

US3752025

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:41:55

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

US3752025

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:41:55

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 ☐

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	13/NOV/2020 15:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	17/NOV/2020 01:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	18/NOV/2020 08:38
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

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	21/NOV/2020 15:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	24/NOV/2020 14:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Feb 2021 18:02:44

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	15/DEC/2020 11:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 31 Mar 2021 14:12:47

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 31 Mar 2021 14:12:47

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	05/FEB/2021 10:40
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

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 31 Mar 2021 14:12:47

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	05/FEB/2021 10:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 31 Mar 2021 14:12:47

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	02/MAR/2021 12:07
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

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 31 Mar 2021 14:12:47

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	12/MAR/2021 08:56
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

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 31 Mar 2021 14:12:47

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	18/MAR/2021 08:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 31 Mar 2021 14:12:47

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	19/MAR/2021 09:40
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

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 31 Mar 2021 14:12:47

Generated On: 10 Jun 2021 09:41:55

SAEID	USA-US113-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	30/MAR/2021 11:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3752025 (Prod: Baptist Health Center for Clinical Research)

US3752025

Form: Participant Creation

Generated On: 10 Jun 2021 09:41:55

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:15:05
User entered 'US3752025'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:54:28

US3752025

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:44:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:04:34

US3752025

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:44:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:54:29

US3752025

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:44:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:04:34

US3752025

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'SCRN'	System	10 Aug 2020 18:04:34

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:54:30

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '58'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'YEARS'	System	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '58'	System	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:46:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:47:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Aug 2020'	System	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2020'	System	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:47:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:47:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:55

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:47:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:47:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:47:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:47:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:54:29

US3752025

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'I'	System	10 Aug 2020 18:04:51

US3752025

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 15:48:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:04:51

US3752025

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:41:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:16:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:56:10

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:47:32
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:59:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:59:20
Data point term sent to Coder	System	11 Aug 2020 13:57:32
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:47:34
User entered 'un UNK 2020'	(b) (4), (b) (6)	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:47:35
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:47:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:47:38
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:47:40
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 2020'	System	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2020'	System	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:48:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:59:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:59:20
Data point term sent to Coder	System	11 Aug 2020 13:57:30
User entered 'Diabetes mellitus type II'	(b) (4), (b) (6)	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:48:16
User entered 'un UNK 2020'	(b) (4), (b) (6)	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:48:17
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:48:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:48:21
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:48:22
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 2020'	System	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2020'	System	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:49:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 06:12:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 06:12:18
Data point term sent to Coder	System	11 Aug 2020 13:58:34
User entered 'GERD/Reflux'	(b) (4), (b) (6)	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:49:39
User entered 'un UNK 2017'	(b) (4), (b) (6)	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:49:41
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:49:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:49:44
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:49:46
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 2017'	System	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2017'	System	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:20:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:20:07
Data point term sent to Coder	System	11 Aug 2020 14:00:35
User entered 'SURGICAL STERILIZATION/hysterectomy' reason for change:	(b) (4), (b) (6)	11 Aug 2020 13:59:58
Data Entry Error		
Data point term sent to Coder	System	11 Aug 2020 13:59:34
User entered 'Surgical sterilization'	(b) (4), (b) (6)	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:10
User entered 'un UNK 1989'	(b) (4), (b) (6)	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:11
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:13
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:15
User entered 'un UNK 1989'	(b) (4), (b) (6)	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:16
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 1989'	System	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '1989'	System	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 1989'	System	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '1989'	System	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:27
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:01:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:01:11
Data point term sent to Coder	System	11 Aug 2020 13:59:34
User entered 'Anxiety'	(b) (4), (b) (6)	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:29
User entered 'un UNK 2019'	(b) (4), (b) (6)	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:30
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:33
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:50:36
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 2019'	System	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2019'	System	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:52:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. '(Site from DM).	(b) (4), (b) (6)	13 Oct 2020 16:26:50
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 10:26:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 10:26:38
Data point term sent to Coder	System	12 Oct 2020 18:12:34
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:12:21
Coding entries removed.	(b) (4), (b) (6)	12 Oct 2020 18:12:14
User entered 'BACK SURGERY (associated condition unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 18:12:14
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. '(Site from DM).	(b) (4), (b) (6)	12 Oct 2020 17:18:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:01:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:01:13
Data point term sent to Coder	System	11 Aug 2020 14:00:35

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
User entered 'Back surgery'	(b) (4), (b) (6)	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:51:09
User entered 'un UNK 1989'	(b) (4), (b) (6)	11 Aug 2020 14:00:31

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:51:11
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:00:31

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:51:13
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:51:15
User entered 'un UNK 1989'	(b) (4), (b) (6)	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 1989'	System	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '1989'	System	11 Aug 2020 14:00:31

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 1989'	System	11 Aug 2020 14:00:31

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '1989'	System	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:52:52
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:36:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 10:26:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 10:26:38
Data point term sent to Coder	System	12 Oct 2020 18:13:34
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:12:51
Coding entries removed.	(b) (4), (b) (6)	12 Oct 2020 18:12:45
User entered 'BACK SURGERY (associated condition unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 18:12:45
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 17:19:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:03:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:03:06
Data point term sent to Coder	System	11 Aug 2020 14:01:35

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
User entered 'Back surgery'	(b) (4), (b) (6)	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:52:34
User entered 'un UNK 2019'	(b) (4), (b) (6)	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:52:56
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:52:58
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:52:59
User entered 'un UNK 2019'	(b) (4), (b) (6)	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:53:02
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 2019'	System	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2019'	System	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 2019'	System	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2019'	System	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:53:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:03:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:03:08
Data point term sent to Coder	System	11 Aug 2020 14:02:36
User entered 'Tonsillectomy'	(b) (4), (b) (6)	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:53:13
User entered 'un UNK 1978'	(b) (4), (b) (6)	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:53:16
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:53:17
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:53:19
User entered 'un UNK 1978'	(b) (4), (b) (6)	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:53:21
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 1978'	System	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '1978'	System	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 1978'	System	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '1978'	System	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:34
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:53:36
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:37:12
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)	12 Oct 2020 18:14:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 18:14:25
Data point term sent to Coder	System	12 Oct 2020 18:13:36
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:13:15
Coding entries removed.	(b) (4), (b) (6)	12 Oct 2020 18:13:09
User entered 'CHOLECYSTECTOMY (associated condition unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 18:13:09
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 17:19:12
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)	11 Aug 2020 14:03:07

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EAB) (1725)

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	11 Aug 2020 14:03:07
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 14:02:37
User entered 'Cholecystectomy'	(b) (4), (b) (6)	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:47:57
User closed query 'Per source, start date is UNK, EDC shows 2004 as start year. Please review and clarify' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 15:47:53
Query 'Per source, start date is UNK, EDC shows 2004 as start year. Please review and clarify' answered with 'data updated' (Site from CRA).	Jamie Pettus (b) (4)	02 Mar 2021 20:09:57
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 16:40:37
User opened query 'Per source, start date is UNK, EDC shows 2004 as start year. Please review and clarify' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:20:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:54:11
User entered 'un UNK 2004'	(b) (4), (b) (6)	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:54:14
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:54:16
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:54:17
User entered 'un UNK 2004'	(b) (4), (b) (6)	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:54:19
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 2004'	System	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2004'	System	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 2004'	System	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2004'	System	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:54:45
User coded data point as SOC: Vascular disorders, HLT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic aneurysm, LLT: Aortic aneurysm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:37:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:37:47
Data point term sent to Coder	System	13 Nov 2020 15:36:12
User entered 'Aortic Aneurysm'	(b) (4), (b) (6)	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:54:47
User entered 'UN UNK 2017'	(b) (4), (b) (6)	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:54:49
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:54:52
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:35:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 15:35:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 15:35:33
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:35:20
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:54:53
User entered 'UN UNK 2017'	(b) (4), (b) (6)	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:54:56
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 2017'	System	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2017'	System	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 2017'	System	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2017'	System	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:57:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:57:45
Data point term sent to Coder	System	13 Nov 2020 15:41:20
User entered 'Asthma'	(b) (4), (b) (6)	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:19
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:22
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:26
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:28
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:43:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:43:47
Data point term sent to Coder	System	13 Nov 2020 15:43:21
User entered 'Chronic Obstructive Pulmonary Disorder'	(b) (4), (b) (6)	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:56
User entered 'l'	(b) (4), (b) (6)	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:41:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:00
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:01
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:23
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:44:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:44:45
Data point term sent to Coder	System	13 Nov 2020 15:44:22
User entered 'Irritable Bowel Syndrome'	(b) (4), (b) (6)	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:26
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:28
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:30
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	13 Nov 2020 20:54:09
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:44:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 15:44:24
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	13 Nov 2020 15:44:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 15:44:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:43:46
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:31
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:34
User entered '0' reason for change: Data Entry Error	Haylee Rowe (b) (4)	13 Nov 2020 20:54:09
User entered '1'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:13:02
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:12
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Pollakiuria, LLT: Urinary frequency - version MedDRA\23.0.	(b) (4)	
	Coder Import (b) (4)	17 Mar 2021 19:34:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	17 Mar 2021 19:33:43
User entered 'URINARY FREQUENCY' reason for change: Data Entry Error	Haylee Rowe (b) (4)	17 Mar 2021 19:33:28
Data point term sent to Coder	(b) (4)	
DataPoint Un-verified.	System	17 Mar 2021 19:30:38
	Haylee Rowe (b) (4)	17 Mar 2021 19:30:37
	(b) (4)	
Coding entries removed.	Haylee Rowe (b) (4)	17 Mar 2021 19:30:37
	(b) (4)	
Signature has been broken.	Haylee Rowe (b) (4)	17 Mar 2021 19:30:37
	(b) (4)	
User entered 'URINARY INFREQUENCY' reason for change: Data Entry Error	Haylee Rowe (b) (4)	17 Mar 2021 19:30:37
User signature succeeded.	(b) (4)	
	Priyantha Wijewardane	12 Feb 2021 18:02:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:56:43
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Pollakiuria, LLT: Urinary frequency - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 15:47:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 15:47:48
Data point term sent to Coder	(b) (4)	
User entered 'Urinary Frequency'	System	13 Nov 2020 15:46:24
	(b) (4), (b) (6)	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:45
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:48
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	13 Nov 2020 16:02:44
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:51:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 15:51:59
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	13 Nov 2020 15:51:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 15:51:59
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:45:59
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	13 Nov 2020 15:45:59
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 15:45:59
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	13 Nov 2020 15:45:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:49
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:50
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 16:02:44
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:57:02
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:08:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:08:47
Data point term sent to Coder	System	13 Nov 2020 16:07:50
User entered 'Generalized Headaches'	(b) (4), (b) (6)	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:57:04
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:57:07
User entered 'l'	(b) (4), (b) (6)	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:57:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:57:11
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:57:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:23:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Spinal osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Jan 2021 22:49:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Jan 2021 22:49:11
Data point term sent to Coder	System	18 Jan 2021 16:04:22
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'data changed' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	18 Jan 2021 16:04:02
Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	18 Jan 2021 16:03:49
User entered 'OsteoARTHRITIS back' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	18 Jan 2021 16:03:49
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 02:34:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:23:49

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	13 Nov 2020 16:23:49
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 16:07:52
User entered 'Arthritis'	(b) (4), (b) (6)	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:58:46
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:58:48
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:58:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:58:55
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:58:58
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:59:10
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:09:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:09:46
Data point term sent to Coder	System	13 Nov 2020 16:08:53
User entered 'Depression'	(b) (4), (b) (6)	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:59:17
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:59:20
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:59:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:59:26
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:59:28
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:00:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:25:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:25:46
Data point term sent to Coder	System	13 Nov 2020 16:09:55
User entered 'Sleep Apnea'	(b) (4), (b) (6)	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:00:18
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:00:20
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:00:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:00:24
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:00:27
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:02:07
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:11:46
Data point term sent to Coder	System	13 Nov 2020 16:10:55
User entered 'Endometriosis'	(b) (4), (b) (6)	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:48:42
User closed query 'Source says start date = unk unk 1989' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 17:48:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
Query 'Source says start date = unk unk 1989' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:42:42
User entered 'un UNK 1989' reason for change:	(b) (4), (b) (6)	17 Nov 2020 22:42:33
Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:02:53
User opened query 'Source says start date = unk unk 1989' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 16:10:44
User entered empty.	(b) (4), (b) (6)	

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:48:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	17 Nov 2020 22:42:48
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 22:42:48
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:42:48
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	17 Nov 2020 22:42:33
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:02:07
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:02:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:02:13
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:02:15
User entered 'l'	(b) (4), (b) (6)	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:41:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 1989'	System	17 Nov 2020 22:42:33
User entered empty.	System	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:41:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '1989'	System	17 Nov 2020 22:42:33
User entered empty.	System	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:03:26
User coded data point as SOC: Surgical and medical procedures, HLT: 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 Nov 2020 16:36:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:36:08
Data point term sent to Coder	System	13 Nov 2020 16:34:29
User entered 'Cholecystectomy'	(b) (4), (b) (6)	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:04:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:41:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:41:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - 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)	19 Nov 2020 18:42:01
	(b) (4)	
Data point term sent to Coder	System	19 Nov 2020 17:32:42
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:32:23
Coding entries removed.	(b) (4), (b) (6)	19 Nov 2020 17:32:23
User entered 'LAPAROSCOPic hysterectomy FOR ENDOMETRIOSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:32:23
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:05:41
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 16:36:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 16:36:09
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 16:35:30
User entered 'Laparoscopy for Endometriosis'	(b) (4), (b) (6)	13 Nov 2020 16:35:07

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User closed query 'Add start date per source' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 04:54:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
Query 'Add start date per source' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:32:31
User entered 'un UNK 1989' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:32:23
User opened query 'Add start date per source' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:05:29
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:35:07

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:32:23
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:32:23
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:04:22
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:35:07

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:05:43
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 16:35:07

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:32:23
User entered 'un UNK 1989' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:32:23
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:04:24
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:35:07

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:32:23
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:32:23
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:04:27
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:35:07

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:41:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 1989'	System	19 Nov 2020 17:32:23
User entered empty.	System	13 Nov 2020 16:35:07

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:41:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '1989'	System	19 Nov 2020 17:32:23
User entered empty.	System	13 Nov 2020 16:35:07

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jan 1989'	System	19 Nov 2020 17:32:23
User entered empty.	System	13 Nov 2020 16:35:07

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '1989'	System	19 Nov 2020 17:32:23
User entered empty.	System	13 Nov 2020 16:35:07

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:05:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:39:49
Data point term sent to Coder	System	13 Nov 2020 16:36:30
User entered 'Tubal Ligation'	(b) (4), (b) (6)	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:06:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:41:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:41:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:39:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:39:48
Data point term sent to Coder	System	13 Nov 2020 16:36:30
User entered 'Wisdom Tooth Extraction'	(b) (4), (b) (6)	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:17
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:19
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:20
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:21
User entered 'l'	(b) (4), (b) (6)	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:41:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:37
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Biopsy breast, LLT: Breast biopsy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 06:00:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 06:00:45
Data point term sent to Coder	System	13 Nov 2020 16:38:32
User entered 'Right Breast Biopsies x 4'	(b) (4), (b) (6)	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:39
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:41
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:43
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:45
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:48
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:41:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Per MM, please clarify MH term ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:09:51
Query 'Per MM, please clarify MH term ' answered with 'here. I've changed it to abuse if this is a coding issue; please let me know if anything else is required' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 14:47:33
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Tobacco abuse, LLT: Tobacco abuse - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 14:46:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 14:46:45
Data point term sent to Coder	System	04 Feb 2021 14:46:18
Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 14:46:16
User entered 'TOBACCO Abuse' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 14:46:16
User opened query 'Per MM, please clarify MH term ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:37:21
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Tobacco user - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:25:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:25:40
Data point term sent to Coder	System	14 Dec 2020 17:24:48
User entered 'TOBACCO USE'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:24:31

US3752025

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	14 Dec 2020 17:24:31
	(b) (4)	

US3752025

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:41:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'l'	(b) (4) Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:24:31

US3752025

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:24:31

US3752025

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:24:31

US3752025

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:24:31

US3752025

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	14 Dec 2020 17:24:31

US3752025

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:41:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	14 Dec 2020 17:24:31

US3752025

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	14 Dec 2020 17:24:31

US3752025

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	14 Dec 2020 17:24:31

US3752025

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:41:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Dec 2020 17:29:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:29:44
Data point term sent to Coder	System	14 Dec 2020 17:28:49
User entered 'CHRONIC BACK PAIN'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:28:02

US3752025

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	14 Dec 2020 17:28:02
	(b) (4)	

US3752025

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:41:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'I'	(b) (4) Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:28:02

US3752025

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:28:02

US3752025

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	14 Dec 2020 17:28:02
	(b) (4)	

US3752025

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:28:02

US3752025

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:41:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	14 Dec 2020 17:28:02

US3752025

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:41:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	14 Dec 2020 17:28:02

US3752025

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	14 Dec 2020 17:28:02

US3752025

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	14 Dec 2020 17:28:02

US3752025

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:41:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal disorders NEC, PT: Renal mass, LLT: Renal mass - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Feb 2021 22:50:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:50:30
Data point term sent to Coder	System	04 Feb 2021 18:50:23
User entered 'LEFT RENAL MASS'	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:50:13

US3752025

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '20 Jul 2020'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:50:13

US3752025

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:41:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:50:13

US3752025

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:41:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:50:13

US3752025

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:41:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:50:13

US3752025

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:41:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:40:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:50:13

US3752025

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:41:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'Jul 2020'	System	04 Feb 2021 18:50:13

US3752025

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:41:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '2020'	System	04 Feb 2021 18:50:13

US3752025

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:41:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	04 Feb 2021 18:50:13

US3752025

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:41:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered empty.	System	04 Feb 2021 18:50:13

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10:58'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered '10 Aug 2020 10:58'	System	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '165.0' cm	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:03:55
DataPoint set to visible.	System	10 Aug 2020 18:04:51

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '244.5' lb	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:03:55
DataPoint set to visible.	System	10 Aug 2020 18:04:51

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
Amendment Manager: User entered '40.82144'	System	16 Sep 2020 23:49:53
User entered '40.8'	System	11 Aug 2020 14:03:55
DataPoint set to visible.	System	10 Aug 2020 18:04:51

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'kg/m2'	System	11 Aug 2020 14:03:55
DataPoint set to visible.	System	10 Aug 2020 18:04:51

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
Query 'Per source,97.8 noted however EDC shows Not Done, Please review and clarify.' canceled (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:57:19
User opened query 'Per source,97.8 noted however EDC shows Not Done, Please review and clarify.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:43:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:37:57
User entered '97.8' F	(b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:14:27
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
Query 'Per source,101 noted however EDC shows Not Done, Please review and clarify' canceled (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:57:21
User opened query 'Per source,101 noted however EDC shows Not Done, Please review and clarify' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:44:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:37:57
User entered '101'	(b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'bpm'	System	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
Query 'Per source,22 noted however EDC shows Not Done, Please review and clarify' canceled (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:57:23
User opened query 'Per source,22 noted however EDC shows Not Done, Please review and clarify' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:44:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:37:57
User entered '22'	(b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'breaths/min'	System	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
Query 'Per source,132 noted however EDC shows Not Done, Please review and clarify' canceled (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:57:26
User opened query 'Per source,132 noted however EDC shows Not Done, Please review and clarify' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:45:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:37:57
User entered '132'	(b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'mmHg'	System	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:57:32
Query 'Per source,78 noted however EDC shows Not Done, Please review and clarify' canceled (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:57:28
User opened query 'Per source,78 noted however EDC shows Not Done, Please review and clarify' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:45:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:37:57
User entered '078'	(b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User entered 'mmHg'	System	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29

US3752025

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:46:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query ' 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 required to be completed using the PE form located in the screening folder. Please ensure physical exam is entered in screening folder or confirm that physical exam was not completed. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:40:17
Query ' 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 required to be completed using the PE form located in the screening folder. Please ensure physical exam is entered in screening folder or confirm that physical exam was not completed. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:46:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 18:46:05
User opened query ' 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 required to be completed using the PE form located in the screening folder. Please ensure physical exam is entered in screening folder or confirm that physical exam was not completed. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:25:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 20:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:53:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:38:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:04:14

US3752025

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:46:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 18:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 20:11:10
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:53:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:38:13
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	11 Aug 2020 14:04:23
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:04:23
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	11 Aug 2020 14:04:14
User entered '19 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:04:14

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:46:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:41:55

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:46:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:41:55

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:46:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 04:52:50
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'Surgically sterile (hysterectomy) listed in MH' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:05:26
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:44:59
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:41:55

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:46:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:41:55

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:46:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'un UNK 1989'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:41:55

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:46:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:41:55

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:46:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:41:55

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:46:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

[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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

[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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Disabled'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

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 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Resides in duplex apartment'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:52:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:46

US3752025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:52:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:46

US3752025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[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 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:52:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:06:46

US3752025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'VISIT1'	System	11 Aug 2020 14:06:46

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:55

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:55:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 16:59:12

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:55

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:55:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:17:10
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:17:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 16:59:12
User entered '143502' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 16:59:12

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:55

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:55:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4)	
	System	11 Aug 2020 14:08:39
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	11 Aug 2020 14:07:03
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 16:59:12

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:55

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 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:55:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:07:03

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:55

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 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:55:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:07:03

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:55

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:55:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet participant is not recorded as at risk. Please reconcile ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:40:18
Query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet participant is not recorded as at risk. Please reconcile ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:51:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 14:51:34
User opened query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet participant is not recorded as at risk. Please reconcile ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 19:15:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:07:03

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:55:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:08:39
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:07:03

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:55:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:07:03

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:39:05
User entered '165.0' cm	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:18:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:39:05
User entered '244.5' lb	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:39:05
User entered '165.0' cm	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:18:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:39:05
User entered '244.5' lb	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10:58'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '10 Aug 2020 10:58'	System	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 14:10:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:10:45
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 14:10:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 14:10:45
User entered '101' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:10:45
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'bpm'	System	11 Aug 2020 14:10:45
User entered empty.	System	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 14:10:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 14:10:45
User entered '22' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:10:45
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'breaths/min'	System	11 Aug 2020 14:10:45
User entered empty.	System	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 14:10:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 14:10:45
User entered '132' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:10:45
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:10:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'mmHg'	System	11 Aug 2020 14:10:45
User entered empty.	System	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 14:10:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 14:10:45
User entered '078' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:10:45
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'mmHg'	System	11 Aug 2020 14:10:45
User entered empty.	System	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:39:05
User entered '165.0' cm	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:18:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:39:05
User entered '244.5' lb	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:49:26
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, vital signs must be taken 30 minutes post dose. ' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:34:35
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 14:10:14
User entered '13:00'	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '10 Aug 2020 13:00'	System	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 14:11:33
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:11:33
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 14:11:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 14:11:33
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:11:33
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'bpm'	System	11 Aug 2020 14:11:33
User entered empty.	System	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 14:11:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 14:11:33
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:11:33
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:10:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'breaths/min'	System	11 Aug 2020 14:11:33
User entered empty.	System	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 14:11:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 14:11:33
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:11:33
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:10:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'mmHg'	System	11 Aug 2020 14:11:33
User entered empty.	System	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:26:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 14:11:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 14:11:33
User entered '078' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:11:33
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:10:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'mmHg'	System	11 Aug 2020 14:11:33
User entered empty.	System	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:29:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
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)	01 Sep 2020 20:24:26
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 'PER CDM: DATA ENTRY CORRECTED.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 16:09:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 16:09:02
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)	01 Sep 2020 14:58:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:16:20

US3752025

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:29:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Sep 2020 16:09:02
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:16:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:31:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:31:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

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 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:31:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:31:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:31:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '12:27'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '10 Aug 2020 12:27'	System	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:31:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:31:51
User entered 'ONCE'	System	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:32:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:24:21

US3752025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:32:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:24:21

US3752025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:32:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '11:04'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:24:21

US3752025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '10 Aug 2020 11:04'	System	11 Aug 2020 14:24:21

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:41:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:32:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:32:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:32:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '11:07'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User entered '10 Aug 2020 11:07'	System	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:32:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:32:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User entered empty.	System	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:32:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:34:58

US3752025

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User entered 'I'	System	11 Aug 2020 14:34:58

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T13:06:54', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4ee4e8bc-8414-45d1-a1b3-2c906e9c9793'	System	10 Aug 2020 18:07:22
User entered 'Yes (Y)'	System	10 Aug 2020 18:07:22

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T13:07:01', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4ee4e8bc-8414-45d1-a1b3-2c906e9c9793'	System	10 Aug 2020 18:07:22
User entered '97.8'	System	10 Aug 2020 18:07:22

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T13:07:08', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4ee4e8bc-8414-45d1-a1b3-2c906e9c9793'	System	10 Aug 2020 18:07:22
User entered 'No (N)'	System	10 Aug 2020 18:07:22

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T13:07:18', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4ee4e8bc-8414-45d1-a1b3-2c906e9c9793'	System	10 Aug 2020 18:07:22
User entered '10 Aug 2020 13:07'	System	10 Aug 2020 18:07:22

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '10 Aug 2020 12:47'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '10 Aug 2020 15:17'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:53:47', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '2959f237-c665-448a-b72c-516ae364e629'	System	11 Aug 2020 00:54:16
User entered 'Yes (Y)'	System	11 Aug 2020 00:54:16

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:53:54', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '2959f237-c665-448a-b72c-516ae364e629'	System	11 Aug 2020 00:54:16
User entered '97.5'	System	11 Aug 2020 00:54:16

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:54:05', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '2959f237-c665-448a-b72c-516ae364e629'	System	11 Aug 2020 00:54:16
User entered 'No (N)'	System	11 Aug 2020 00:54:16

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:54:12', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '2959f237-c665-448a-b72c-516ae364e629'	System	11 Aug 2020 00:54:16
User entered '10 Aug 2020 19:54'	System	11 Aug 2020 00:54:16

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '10 Aug 2020 16:12'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 2'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:35:15', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '235841aa-7e65-4c47-9cf3-6414751adb5a'	System	11 Aug 2020 17:35:35
User entered 'Yes (Y)'	System	11 Aug 2020 17:35:35

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:35:22', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '235841aa-7e65-4c47-9cf3-6414751adb5a' User entered '97.7'	System	11 Aug 2020 17:35:35
	System	11 Aug 2020 17:35:35

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:35:27', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '235841aa-7e65-4c47-9cf3-6414751adb5a'	System	11 Aug 2020 17:35:35
User entered 'No (N)'	System	11 Aug 2020 17:35:35

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:35:32', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '235841aa-7e65-4c47-9cf3-6414751adb5a'	System	11 Aug 2020 17:35:35
User entered '11 Aug 2020 12:35'	System	11 Aug 2020 17:35:35

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 3'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:15:25', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c7b5b4b-bac9-42f7-816a-a2df384ec5df'	System	12 Aug 2020 17:15:45
User entered 'Yes (Y)'	System	12 Aug 2020 17:15:45

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:15:33', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c7b5b4b-bac9-42f7-816a-a2df384ec5df'	System	12 Aug 2020 17:15:45
User entered '98.1'	System	12 Aug 2020 17:15:45

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:15:40', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c7b5b4b-bac9-42f7-816a-a2df384ec5df'	System	12 Aug 2020 17:15:45
User entered 'No (N)'	System	12 Aug 2020 17:15:45

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:15:43', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c7b5b4b-bac9-42f7-816a-a2df384ec5df'	System	12 Aug 2020 17:15:45
User entered '12 Aug 2020 12:15'	System	12 Aug 2020 17:15:45

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 4'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:54:07', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'ce20f04d-f1bf-49a0-9253-2b869dfcc110'	System	13 Aug 2020 17:54:23
User entered 'Yes (Y)'	System	13 Aug 2020 17:54:23

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:54:13', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'ce20f04d-f1bf-49a0-9253-2b869dfcc110'	System	13 Aug 2020 17:54:23
User entered '97.7'	System	13 Aug 2020 17:54:23

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:54:18', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'ce20f04d-f1bf-49a0-9253-2b869dfcc110'	System	13 Aug 2020 17:54:23
User entered 'No (N)'	System	13 Aug 2020 17:54:23

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:54:21', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'ce20f04d-f1bf-49a0-9253-2b869dfcc110'	System	13 Aug 2020 17:54:23
User entered '13 Aug 2020 12:54'	System	13 Aug 2020 17:54:23

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 5'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:10:58', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '3ba45432-9a08-4422-81af-9c11d416560f'	System	14 Aug 2020 18:11:14
User entered 'Yes (Y)'	System	14 Aug 2020 18:11:14

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:04', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '3ba45432-9a08-4422-81af-9c11d416560f' User entered '98.2'	System	14 Aug 2020 18:11:14
	System	14 Aug 2020 18:11:14

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:08', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '3ba45432-9a08-4422-81af-9c11d416560f'	System	14 Aug 2020 18:11:14
User entered 'No (N)'	System	14 Aug 2020 18:11:14

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:12', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '3ba45432-9a08-4422-81af-9c11d416560f'	System	14 Aug 2020 18:11:14
User entered '14 Aug 2020 13:11'	System	14 Aug 2020 18:11:14

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 6'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:08:22', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '852d992f-bc70-4ee9-a39a-2b64bf9d509e'	System	15 Aug 2020 18:08:37
User entered 'Yes (Y)'	System	15 Aug 2020 18:08:37

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:08:27', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '852d992f-bc70-4ee9-a39a-2b64bf9d509e'	System	15 Aug 2020 18:08:37
User entered '98.0'	System	15 Aug 2020 18:08:37

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:08:31', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '852d992f-bc70-4ee9-a39a-2b64bf9d509e'	System	15 Aug 2020 18:08:37
User entered 'No (N)'	System	15 Aug 2020 18:08:37

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:08:35', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '852d992f-bc70-4ee9-a39a-2b64bf9d509e'	System	15 Aug 2020 18:08:37
User entered '15 Aug 2020 13:08'	System	15 Aug 2020 18:08:37

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 7'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:36:21', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bc47b265-c4dc-4939-8ffd-2dec195bf50e'	System	16 Aug 2020 17:36:42
User entered 'Yes (Y)'	System	16 Aug 2020 17:36:42

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:36:29', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bc47b265-c4dc-4939-8ffd-2dec195bf50e'	System	16 Aug 2020 17:36:42
User entered '98.1'	System	16 Aug 2020 17:36:42

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:36:33', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bc47b265-c4dc-4939-8ffd-2dec195bf50e'	System	16 Aug 2020 17:36:42
User entered 'No (N)'	System	16 Aug 2020 17:36:42

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:36:39', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bc47b265-c4dc-4939-8ffd-2dec195bf50e'	System	16 Aug 2020 17:36:42
User entered '16 Aug 2020 12:36'	System	16 Aug 2020 17:36:42

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T13:07:34', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'df89fdd3-7469-48fb-b516-01df6642c4e9'	System	10 Aug 2020 18:08:00
User entered 'None (1)'	System	10 Aug 2020 18:08:00

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T13:07:40', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'df89fdd3-7469-48fb-b516-01df6642c4e9'	System	10 Aug 2020 18:08:00
User entered 'No (N)'	System	10 Aug 2020 18:08:00

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T13:07:43', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'df89fdd3-7469-48fb-b516-01df6642c4e9'	System	10 Aug 2020 18:08:00
User entered 'No (N)'	System	10 Aug 2020 18:08:00

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T13:07:50', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'df89fdd3-7469-48fb-b516-01df6642c4e9'	System	10 Aug 2020 18:08:00
User entered 'None (1)'	System	10 Aug 2020 18:08:00

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T13:07:56', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'df89fdd3-7469-48fb-b516-01df6642c4e9'	System	10 Aug 2020 18:08:00
User entered '10 Aug 2020 13:07'	System	10 Aug 2020 18:08:00

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '10 Aug 2020 12:47'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '10 Aug 2020 15:17'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:54:24', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '07add1ad-b4e2-460f-9c7e-eed6d524d4d6'	System	11 Aug 2020 00:54:54
User entered 'None (1)'	System	11 Aug 2020 00:54:54

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:54:29', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '07add1ad-b4e2-460f-9c7e-eed6d524d4d6'	System	11 Aug 2020 00:54:54
User entered 'No (N)'	System	11 Aug 2020 00:54:54

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:54:36', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '07add1ad-b4e2-460f-9c7e-eed6d524d4d6'	System	11 Aug 2020 00:54:54
User entered 'No (N)'	System	11 Aug 2020 00:54:54

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:54:45', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '07add1ad-b4e2-460f-9c7e-eed6d524d4d6'	System	11 Aug 2020 00:54:54
User entered 'None (1)'	System	11 Aug 2020 00:54:54

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:54:50', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '07add1ad-b4e2-460f-9c7e-eed6d524d4d6'	System	11 Aug 2020 00:54:54
User entered '10 Aug 2020 19:54'	System	11 Aug 2020 00:54:54

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '10 Aug 2020 16:12'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 2'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:35:39', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'e40c727c-ec7a-4362-8f18-ba3a2a70f9cc'	System	11 Aug 2020 17:36:12
User entered 'None (1)'	System	11 Aug 2020 17:36:12

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:35:53', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'e40c727c-ec7a-4362-8f18-ba3a2a70f9cc'	System	11 Aug 2020 17:36:12
User entered 'No (N)'	System	11 Aug 2020 17:36:12

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:35:59', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'e40c727c-ec7a-4362-8f18-ba3a2a70f9cc'	System	11 Aug 2020 17:36:12
User entered 'No (N)'	System	11 Aug 2020 17:36:12

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:36:03', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'e40c727c-ec7a-4362-8f18-ba3a2a70f9cc'	System	11 Aug 2020 17:36:12
User entered 'None (1)'	System	11 Aug 2020 17:36:12

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:36:07', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'e40c727c-ec7a-4362-8f18-ba3a2a70f9cc'	System	11 Aug 2020 17:36:12
User entered '11 Aug 2020 12:36'	System	11 Aug 2020 17:36:12

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 3'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:15:53', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'cb5b0cf5-ab63-4c0a-bc2b-47ce225ee49a'	System	12 Aug 2020 17:16:13
User entered 'None (1)'	System	12 Aug 2020 17:16:13

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:15:57', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'cb5b0cf5-ab63-4c0a-bc2b-47ce225ee49a'	System	12 Aug 2020 17:16:13
User entered 'No (N)'	System	12 Aug 2020 17:16:13

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:01', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'cb5b0cf5-ab63-4c0a-bc2b-47ce225ee49a'	System	12 Aug 2020 17:16:13
User entered 'No (N)'	System	12 Aug 2020 17:16:13

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:07', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'cb5b0cf5-ab63-4c0a-bc2b-47ce225ee49a'	System	12 Aug 2020 17:16:13
User entered 'None (1)'	System	12 Aug 2020 17:16:13

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:11', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'cb5b0cf5-ab63-4c0a-bc2b-47ce225ee49a'	System	12 Aug 2020 17:16:13
User entered '12 Aug 2020 12:16'	System	12 Aug 2020 17:16:13

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 4'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:54:37', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '77a8118e-29d8-46e5-b59e-bc6353aaf223'	System	13 Aug 2020 17:54:51
User entered 'None (1)'	System	13 Aug 2020 17:54:51

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:54:34', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '77a8118e-29d8-46e5-b59e-bc6353aaf223'	System	13 Aug 2020 17:54:51
User entered 'No (N)'	System	13 Aug 2020 17:54:51

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:54:40', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '77a8118e-29d8-46e5-b59e-bc6353aaf223'	System	13 Aug 2020 17:54:51
User entered 'No (N)'	System	13 Aug 2020 17:54:51

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:54:43', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '77a8118e-29d8-46e5-b59e-bc6353aaf223'	System	13 Aug 2020 17:54:51
User entered 'None (1)'	System	13 Aug 2020 17:54:51

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:54:46', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '77a8118e-29d8-46e5-b59e-bc6353aaf223'	System	13 Aug 2020 17:54:51
User entered '13 Aug 2020 12:54'	System	13 Aug 2020 17:54:51

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 5'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:17', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'cda2dbc2-8e9e-484a-a410-f52ba4ad5a79'	System	14 Aug 2020 18:11:32
User entered 'None (1)'	System	14 Aug 2020 18:11:32

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:20', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'cda2dbc2-8e9e-484a-a410-f52ba4ad5a79'	System	14 Aug 2020 18:11:32
User entered 'No (N)'	System	14 Aug 2020 18:11:32

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:23', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'cda2dbc2-8e9e-484a-a410-f52ba4ad5a79'	System	14 Aug 2020 18:11:32
User entered 'No (N)'	System	14 Aug 2020 18:11:32

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:26', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'cda2dbc2-8e9e-484a-a410-f52ba4ad5a79'	System	14 Aug 2020 18:11:32
User entered 'None (1)'	System	14 Aug 2020 18:11:32

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:28', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'cda2dbc2-8e9e-484a-a410-f52ba4ad5a79'	System	14 Aug 2020 18:11:32
User entered '14 Aug 2020 13:11'	System	14 Aug 2020 18:11:32

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 6'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:08:42', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'e321d410-56b4-44f4-86c5-b0da0f23c78c'	System	15 Aug 2020 18:08:59
User entered 'None (1)'	System	15 Aug 2020 18:08:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:08:46', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'e321d410-56b4-44f4-86c5-b0da0f23c78c'	System	15 Aug 2020 18:08:59
User entered 'No (N)'	System	15 Aug 2020 18:08:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:08:49', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'e321d410-56b4-44f4-86c5-b0da0f23c78c'	System	15 Aug 2020 18:08:59
User entered 'No (N)'	System	15 Aug 2020 18:08:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:08:51', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'e321d410-56b4-44f4-86c5-b0da0f23c78c'	System	15 Aug 2020 18:08:59
User entered 'None (1)'	System	15 Aug 2020 18:08:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:08:56', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'e321d410-56b4-44f4-86c5-b0da0f23c78c'	System	15 Aug 2020 18:08:59
User entered '15 Aug 2020 13:08'	System	15 Aug 2020 18:08:59

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 7'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:36:44', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'f326e116-6411-473e-8244-59ed67ba748b'	System	16 Aug 2020 17:37:10
User entered 'None (1)'	System	16 Aug 2020 17:37:10

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:36:47', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'f326e116-6411-473e-8244-59ed67ba748b'	System	16 Aug 2020 17:37:10
User entered 'No (N)'	System	16 Aug 2020 17:37:10

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:36:56', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'f326e116-6411-473e-8244-59ed67ba748b'	System	16 Aug 2020 17:37:10
User entered 'No (N)'	System	16 Aug 2020 17:37:10

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:37:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'f326e116-6411-473e-8244-59ed67ba748b'	System	16 Aug 2020 17:37:10
User entered 'None (1)'	System	16 Aug 2020 17:37:10

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:37:06', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'f326e116-6411-473e-8244-59ed67ba748b'	System	16 Aug 2020 17:37:10
User entered '16 Aug 2020 12:37'	System	16 Aug 2020 17:37:10

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '10 Aug 2020 12:47'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '10 Aug 2020 15:17'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:55:02', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '7fa892f8-59f7-4f4c-9923-0422e75a9401'	System	11 Aug 2020 00:55:49
User entered 'None (0)'	System	11 Aug 2020 00:55:49

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:55:08', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '7fa892f8-59f7-4f4c-9923-0422e75a9401'	System	11 Aug 2020 00:55:49
User entered 'None (0)'	System	11 Aug 2020 00:55:49

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:55:16', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '7fa892f8-59f7-4f4c-9923-0422e75a9401'	System	11 Aug 2020 00:55:49
User entered 'None (0)'	System	11 Aug 2020 00:55:49

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:55:21', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '7fa892f8-59f7-4f4c-9923-0422e75a9401'	System	11 Aug 2020 00:55:49
User entered 'None (0)'	System	11 Aug 2020 00:55:49

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:55:28', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '7fa892f8-59f7-4f4c-9923-0422e75a9401'	System	11 Aug 2020 00:55:49
User entered 'None (0)'	System	11 Aug 2020 00:55:49

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:55:31', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '7fa892f8-59f7-4f4c-9923-0422e75a9401'	System	11 Aug 2020 00:55:49
User entered 'None (0)'	System	11 Aug 2020 00:55:49

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:55:38', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '7fa892f8-59f7-4f4c-9923-0422e75a9401'	System	11 Aug 2020 00:55:49
User entered 'No (N)'	System	11 Aug 2020 00:55:49

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-10T19:55:45', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '7fa892f8-59f7-4f4c-9923-0422e75a9401'	System	11 Aug 2020 00:55:49
User entered '10 Aug 2020 19:55'	System	11 Aug 2020 00:55:49

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '10 Aug 2020 16:12'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 2'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:36:13', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c44eaf96-61c4-468d-bd24-b9e611950910'	System	11 Aug 2020 17:36:41
User entered 'None (0)'	System	11 Aug 2020 17:36:41

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:36:16', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c44eaf96-61c4-468d-bd24-b9e611950910'	System	11 Aug 2020 17:36:41
User entered 'None (0)'	System	11 Aug 2020 17:36:41

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:36:20', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c44eaf96-61c4-468d-bd24-b9e611950910'	System	11 Aug 2020 17:36:41
User entered 'None (0)'	System	11 Aug 2020 17:36:41

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:36:24', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c44eaf96-61c4-468d-bd24-b9e611950910'	System	11 Aug 2020 17:36:41
User entered 'None (0)'	System	11 Aug 2020 17:36:41

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:36:28', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c44eaf96-61c4-468d-bd24-b9e611950910'	System	11 Aug 2020 17:36:41
User entered 'None (0)'	System	11 Aug 2020 17:36:41

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:36:31', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c44eaf96-61c4-468d-bd24-b9e611950910'	System	11 Aug 2020 17:36:41
User entered 'None (0)'	System	11 Aug 2020 17:36:41

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:36:35', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c44eaf96-61c4-468d-bd24-b9e611950910'	System	11 Aug 2020 17:36:41
User entered 'No (N)'	System	11 Aug 2020 17:36:41

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-11T12:36:38', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c44eaf96-61c4-468d-bd24-b9e611950910'	System	11 Aug 2020 17:36:41
User entered '11 Aug 2020 12:36'	System	11 Aug 2020 17:36:41

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 3'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:19', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37117f51-6e4f-48c6-9cd7-3c3dc36633ca'	System	12 Aug 2020 17:16:50
User entered 'None (0)'	System	12 Aug 2020 17:16:50

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:26', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37117f51-6e4f-48c6-9cd7-3c3dc36633ca'	System	12 Aug 2020 17:16:50
User entered 'None (0)'	System	12 Aug 2020 17:16:50

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:29', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37117f51-6e4f-48c6-9cd7-3c3dc36633ca'	System	12 Aug 2020 17:16:50
User entered 'None (0)'	System	12 Aug 2020 17:16:50

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:32', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37117f51-6e4f-48c6-9cd7-3c3dc36633ca'	System	12 Aug 2020 17:16:50
User entered 'None (0)'	System	12 Aug 2020 17:16:50

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:35', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37117f51-6e4f-48c6-9cd7-3c3dc36633ca'	System	12 Aug 2020 17:16:50
User entered 'None (0)'	System	12 Aug 2020 17:16:50

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:38', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37117f51-6e4f-48c6-9cd7-3c3dc36633ca'	System	12 Aug 2020 17:16:50
User entered 'None (0)'	System	12 Aug 2020 17:16:50

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:42', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37117f51-6e4f-48c6-9cd7-3c3dc36633ca'	System	12 Aug 2020 17:16:50
User entered 'No (N)'	System	12 Aug 2020 17:16:50

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-12T12:16:48', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37117f51-6e4f-48c6-9cd7-3c3dc36633ca'	System	12 Aug 2020 17:16:50
User entered '12 Aug 2020 12:16'	System	12 Aug 2020 17:16:50

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 4'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:54:51', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'a3ac3e87-b692-4049-8408-505d525f0f6e'	System	13 Aug 2020 17:55:24
User entered 'None (0)'	System	13 Aug 2020 17:55:24

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:55:01', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'a3ac3e87-b692-4049-8408-505d525f0f6e'	System	13 Aug 2020 17:55:24
User entered 'None (0)'	System	13 Aug 2020 17:55:24

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:55:04', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'a3ac3e87-b692-4049-8408-505d525f0f6e'	System	13 Aug 2020 17:55:24
User entered 'None (0)'	System	13 Aug 2020 17:55:24

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:55:09', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'a3ac3e87-b692-4049-8408-505d525f0f6e'	System	13 Aug 2020 17:55:24
User entered 'None (0)'	System	13 Aug 2020 17:55:24

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:55:11', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'a3ac3e87-b692-4049-8408-505d525f0f6e'	System	13 Aug 2020 17:55:24
User entered 'None (0)'	System	13 Aug 2020 17:55:24

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:55:14', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'a3ac3e87-b692-4049-8408-505d525f0f6e'	System	13 Aug 2020 17:55:24
User entered 'None (0)'	System	13 Aug 2020 17:55:24

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:55:18', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'a3ac3e87-b692-4049-8408-505d525f0f6e'	System	13 Aug 2020 17:55:24
User entered 'No (N)'	System	13 Aug 2020 17:55:24

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-13T12:55:21', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'a3ac3e87-b692-4049-8408-505d525f0f6e'	System	13 Aug 2020 17:55:24
User entered '13 Aug 2020 12:55'	System	13 Aug 2020 17:55:24

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 5'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:33', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b1b9e547-397b-4156-8675-4443a715cbc1' User entered 'None (0)'	System	14 Aug 2020 18:11:59
	System	14 Aug 2020 18:11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:36', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b1b9e547-397b-4156-8675-4443a715cbc1'	System	14 Aug 2020 18:11:59
User entered 'None (0)'	System	14 Aug 2020 18:11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:38', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b1b9e547-397b-4156-8675-4443a715cbc1' User entered 'None (0)'	System	14 Aug 2020 18:11:59
	System	14 Aug 2020 18:11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:40', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b1b9e547-397b-4156-8675-4443a715cbc1'	System	14 Aug 2020 18:11:59
User entered 'None (0)'	System	14 Aug 2020 18:11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:44', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b1b9e547-397b-4156-8675-4443a715cbc1' User entered 'None (0)'	System	14 Aug 2020 18:11:59
	System	14 Aug 2020 18:11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:47', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b1b9e547-397b-4156-8675-4443a715cbc1'	System	14 Aug 2020 18:11:59
User entered 'None (0)'	System	14 Aug 2020 18:11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:51', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b1b9e547-397b-4156-8675-4443a715cbc1'	System	14 Aug 2020 18:11:59
User entered 'No (N)'	System	14 Aug 2020 18:11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-14T13:11:54', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b1b9e547-397b-4156-8675-4443a715cbc1'	System	14 Aug 2020 18:11:59
User entered '14 Aug 2020 13:11'	System	14 Aug 2020 18:11:59

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 6'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:09:01', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b750837f-1f63-461a-993d-0ea4ee976134'	System	15 Aug 2020 18:09:27
User entered 'None (0)'	System	15 Aug 2020 18:09:27

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:09:03', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b750837f-1f63-461a-993d-0ea4ee976134'	System	15 Aug 2020 18:09:27
User entered 'None (0)'	System	15 Aug 2020 18:09:27

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:09:06', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b750837f-1f63-461a-993d-0ea4ee976134'	System	15 Aug 2020 18:09:27
User entered 'None (0)'	System	15 Aug 2020 18:09:27

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:09:08', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b750837f-1f63-461a-993d-0ea4ee976134'	System	15 Aug 2020 18:09:27
User entered 'None (0)'	System	15 Aug 2020 18:09:27

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:09:11', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b750837f-1f63-461a-993d-0ea4ee976134'	System	15 Aug 2020 18:09:27
User entered 'None (0)'	System	15 Aug 2020 18:09:27

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:09:14', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b750837f-1f63-461a-993d-0ea4ee976134'	System	15 Aug 2020 18:09:27
User entered 'None (0)'	System	15 Aug 2020 18:09:27

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:09:20', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b750837f-1f63-461a-993d-0ea4ee976134'	System	15 Aug 2020 18:09:27
User entered 'No (N)'	System	15 Aug 2020 18:09:27

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-15T13:09:23', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b750837f-1f63-461a-993d-0ea4ee976134'	System	15 Aug 2020 18:09:27
User entered '15 Aug 2020 13:09'	System	15 Aug 2020 18:09:27

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 7'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:37:18', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b5a75dad-266b-41c2-8168-de61590ccb20'	System	16 Aug 2020 17:37:43
User entered 'None (0)'	System	16 Aug 2020 17:37:43

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:37:21', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b5a75dad-266b-41c2-8168-de61590ccb20'	System	16 Aug 2020 17:37:43
User entered 'None (0)'	System	16 Aug 2020 17:37:43

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:37:23', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b5a75dad-266b-41c2-8168-de61590ccb20'	System	16 Aug 2020 17:37:43
User entered 'None (0)'	System	16 Aug 2020 17:37:43

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:37:26', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b5a75dad-266b-41c2-8168-de61590ccb20'	System	16 Aug 2020 17:37:43
User entered 'None (0)'	System	16 Aug 2020 17:37:43

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:37:28', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b5a75dad-266b-41c2-8168-de61590ccb20' User entered 'None (0)'	System	16 Aug 2020 17:37:43
	System	16 Aug 2020 17:37:43

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:37:31', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b5a75dad-266b-41c2-8168-de61590ccb20'	System	16 Aug 2020 17:37:43
User entered 'None (0)'	System	16 Aug 2020 17:37:43

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:37:35', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b5a75dad-266b-41c2-8168-de61590ccb20'	System	16 Aug 2020 17:37:43
User entered 'No (N)'	System	16 Aug 2020 17:37:43

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-08-16T12:37:39', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b5a75dad-266b-41c2-8168-de61590ccb20'	System	16 Aug 2020 17:37:43
User entered '16 Aug 2020 12:37'	System	16 Aug 2020 17:37:43

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:05:20

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 00:12:14

US3752025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 00:12:14

US3752025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 00:12:14

US3752025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 00:12:14

US3752025

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:14:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:21:14

US3752025

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User entered 'I'	System	27 Aug 2020 18:21:14

US3752025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:15:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:29:49

US3752025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:11:42
User closed query 'Please review and clarify between source=24Aug2020 and EDC=25Aug2020' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 16:11:40
Query 'Please review and clarify between source=24Aug2020 and EDC=25Aug2020' answered with 'DATA ENTRY ERROR' (Site from CRA).	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:36:48
Signature has been broken.	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:36:37
User entered '24 Aug 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:36:37
User opened query 'Please review and clarify between source=24Aug2020 and EDC=25Aug2020' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 18:16:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:29:49

US3752025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:15:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:29:49

US3752025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:15:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:29:49

US3752025

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:16:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:23:34

US3752025

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User entered 'I'	System	21 Sep 2020 15:23:34

US3752025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:25:45
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:14:40

US3752025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:25:45
User entered '31 Aug 2020'	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:14:40

US3752025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:25:45
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:14:40

US3752025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:25:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:14:40

US3752025

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
Query 'Please complete SCD22 eCRF' canceled (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:25:51
User opened query 'Please complete SCD22 eCRF' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 18:17:57
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:17:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:23:46

US3752025

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User entered 'I'	System	21 Sep 2020 15:23:46

US3752025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:27:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:24:01

US3752025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:27:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 20:17:07
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'dates confirmed' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 17:14:39
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	21 Sep 2020 15:24:01
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:24:01

US3752025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[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 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:27:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:24:01

US3752025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'VISIT2'	System	21 Sep 2020 15:24:01

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '09:21'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '21 Sep 2020 09:21'	System	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 20:23:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 20:23:01
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 20:23:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 20:23:01
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'bpm'	System	21 Sep 2020 20:23:01
User entered empty.	System	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 20:23:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 20:23:01
User entered '17' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'breaths/min'	System	21 Sep 2020 20:23:01
User entered empty.	System	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 20:23:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 20:23:01
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'mmHg'	System	21 Sep 2020 20:23:01
User entered empty.	System	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 20:23:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 20:23:01
User entered '82' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'mmHg'	System	21 Sep 2020 20:23:01
User entered empty.	System	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Per CDM: Post-dose vital signs time is prior to or less than 30 minutes after the Dose Time. Please review and reconcile ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:44:15
Query 'Per CDM: Post-dose vital signs time is prior to or less than 30 minutes after the Dose Time. Please review and reconcile ' answered with 'Time is correct. Site miscalculated time vitals were to be obtained. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:12:14
User opened query 'Per CDM: Post-dose vital signs time is prior to or less than 30 minutes after the Dose Time. Please review and reconcile ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:31:48
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:23:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 20:23:47
User entered '10:35' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:47
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '21 Sep 2020 10:35'	System	21 Sep 2020 20:23:47
User entered empty.	System	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 20:23:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 20:23:47
User entered '99.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:47
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:47
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 20:23:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 20:23:47
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:47
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'bpm'	System	21 Sep 2020 20:23:47
User entered empty.	System	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 20:23:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 20:23:47
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:47
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'breaths/min'	System	21 Sep 2020 20:23:47
User entered empty.	System	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 20:23:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 20:23:47
User entered '122' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:47
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'mmHg'	System	21 Sep 2020 20:23:47
User entered empty.	System	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:35:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 20:23:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 20:23:47
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:23:47
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:22:31
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'mmHg'	System	21 Sep 2020 20:23:47
User entered empty.	System	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:59

US3752025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:59

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

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 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10:19'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '21 Sep 2020 10:19'	System	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:29
User entered 'ONCE'	System	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:32

US3752025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:32

US3752025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '09:42'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:32

US3752025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '21 Sep 2020 09:42'	System	21 Sep 2020 20:24:32

US3752025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:41:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:44

US3752025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 20:24:44

US3752025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:44

US3752025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '09:39'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:44

US3752025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '21 Sep 2020 09:39'	System	21 Sep 2020 20:24:44

US3752025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 20:24:44

US3752025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:44

US3752025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:44

US3752025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered empty.	System	21 Sep 2020 20:24:44

US3752025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:38:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:49

US3752025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'I'	System	21 Sep 2020 20:24:49

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:39:36', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '14ec1d1e-a3d0-449b-8438-7d75255aeb32'	System	21 Sep 2020 15:40:12
User entered 'Yes (Y)'	System	21 Sep 2020 15:40:12

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:39:57', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '14ec1d1e-a3d0-449b-8438-7d75255aeb32'	System	21 Sep 2020 15:40:12
User entered '99.0'	System	21 Sep 2020 15:40:12

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:40:02', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '14ec1d1e-a3d0-449b-8438-7d75255aeb32'	System	21 Sep 2020 15:40:12
User entered 'No (N)'	System	21 Sep 2020 15:40:12

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:40:08', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '14ec1d1e-a3d0-449b-8438-7d75255aeb32'	System	21 Sep 2020 15:40:12
User entered '21 Sep 2020 10:40'	System	21 Sep 2020 15:40:12

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '21 Sep 2020 10:39'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '21 Sep 2020 13:09'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:07:12', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '9a721245-7977-498b-86f0-f6bbacaa5d76'	System	22 Sep 2020 01:07:46
User entered 'Yes (Y)'	System	22 Sep 2020 01:07:46

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:07:22', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '9a721245-7977-498b-86f0-f6bbacaa5d76'	System	22 Sep 2020 01:07:46
User entered '97.6'	System	22 Sep 2020 01:07:46

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:07:33', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '9a721245-7977-498b-86f0-f6bbacaa5d76'	System	22 Sep 2020 01:07:46
User entered 'No (N)'	System	22 Sep 2020 01:07:46

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:07:41', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '9a721245-7977-498b-86f0-f6bbacaa5d76'	System	22 Sep 2020 01:07:46
User entered '21 Sep 2020 20:07'	System	22 Sep 2020 01:07:46

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '21 Sep 2020 14:04'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 2'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:23:57', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'f8430a54-aefa-4c32-a720-7a4bca2996e0'	System	22 Sep 2020 18:24:20
User entered 'Yes (Y)'	System	22 Sep 2020 18:24:20

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:05', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'f8430a54-aefa-4c32-a720-7a4bca2996e0'	System	22 Sep 2020 18:24:20
User entered '98.2'	System	22 Sep 2020 18:24:20

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:10', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'f8430a54-aefa-4c32-a720-7a4bca2996e0'	System	22 Sep 2020 18:24:20
User entered 'No (N)'	System	22 Sep 2020 18:24:20

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:15', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'f8430a54-aefa-4c32-a720-7a4bca2996e0'	System	22 Sep 2020 18:24:20
User entered '22 Sep 2020 13:24'	System	22 Sep 2020 18:24:20

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 3'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:16:41', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '09283d44-5b01-4685-a148-71ad2d265342'	System	24 Sep 2020 01:17:00
User entered 'Yes (Y)'	System	24 Sep 2020 01:17:00

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:16:48', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '09283d44-5b01-4685-a148-71ad2d265342'	System	24 Sep 2020 01:17:00
User entered '98.2'	System	24 Sep 2020 01:17:00

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:16:52', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '09283d44-5b01-4685-a148-71ad2d265342'	System	24 Sep 2020 01:17:00
User entered 'No (N)'	System	24 Sep 2020 01:17:00

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:16:56', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '09283d44-5b01-4685-a148-71ad2d265342'	System	24 Sep 2020 01:17:00
User entered '23 Sep 2020 20:16'	System	24 Sep 2020 01:17:00

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 4'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:35:48', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b28ebd85-27c9-40aa-bbca-f30c7a81c4b0'	System	24 Sep 2020 17:36:04
User entered 'Yes (Y)'	System	24 Sep 2020 17:36:04

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:35:54', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b28ebd85-27c9-40aa-bbca-f30c7a81c4b0'	System	24 Sep 2020 17:36:04
User entered '97.7'	System	24 Sep 2020 17:36:04

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:35:56', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b28ebd85-27c9-40aa-bbca-f30c7a81c4b0'	System	24 Sep 2020 17:36:04
User entered 'No (N)'	System	24 Sep 2020 17:36:04

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b28ebd85-27c9-40aa-bbca-f30c7a81c4b0'	System	24 Sep 2020 17:36:04
User entered '24 Sep 2020 12:36'	System	24 Sep 2020 17:36:04

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 5'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:23', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '97b48c29-2ce3-4416-9fc3-ef3101906662'	System	25 Sep 2020 23:37:39
User entered 'Yes (Y)'	System	25 Sep 2020 23:37:39

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:28', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '97b48c29-2ce3-4416-9fc3-ef3101906662'	System	25 Sep 2020 23:37:39
User entered '97.6'	System	25 Sep 2020 23:37:39

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:31', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '97b48c29-2ce3-4416-9fc3-ef3101906662'	System	25 Sep 2020 23:37:39
User entered 'No (N)'	System	25 Sep 2020 23:37:39

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:34', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '97b48c29-2ce3-4416-9fc3-ef3101906662'	System	25 Sep 2020 23:37:39
User entered '25 Sep 2020 18:37'	System	25 Sep 2020 23:37:39

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 6'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:00:31', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b288aab9-fb0b-4be8-a7d5-d5aaef31d4a8'	System	26 Sep 2020 17:01:02
User entered 'Yes (Y)'	System	26 Sep 2020 17:01:02

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:00:39', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b288aab9-fb0b-4be8-a7d5-d5aaef31d4a8'	System	26 Sep 2020 17:01:02
User entered '98.2'	System	26 Sep 2020 17:01:02

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:00:43', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b288aab9-fb0b-4be8-a7d5-d5aaef31d4a8'	System	26 Sep 2020 17:01:02
User entered 'No (N)'	System	26 Sep 2020 17:01:02

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:00:46', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b288aab9-fb0b-4be8-a7d5-d5aaef31d4a8'	System	26 Sep 2020 17:01:02
User entered '26 Sep 2020 12:00'	System	26 Sep 2020 17:01:02

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 7'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:15:32', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bfdbaa4f-c550-4847-b36b-9cf882b9880d'	System	27 Sep 2020 17:15:50
User entered 'Yes (Y)'	System	27 Sep 2020 17:15:50

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:15:39', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bfdbaa4f-c550-4847-b36b-9cf882b9880d'	System	27 Sep 2020 17:15:50
User entered '97.7'	System	27 Sep 2020 17:15:50

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:15:42', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bfdbaa4f-c550-4847-b36b-9cf882b9880d'	System	27 Sep 2020 17:15:50
User entered 'No (N)'	System	27 Sep 2020 17:15:50

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:15:45', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bfdbaa4f-c550-4847-b36b-9cf882b9880d'	System	27 Sep 2020 17:15:50
User entered '27 Sep 2020 12:15'	System	27 Sep 2020 17:15:50

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:40:26', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '75fccedf-2465-44da-bc6a-d692da6738de'	System	21 Sep 2020 15:42:13
User entered 'None (1)'	System	21 Sep 2020 15:42:13

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:40:30', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '75fccedf-2465-44da-bc6a-d692da6738de'	System	21 Sep 2020 15:42:13
User entered 'No (N)'	System	21 Sep 2020 15:42:13

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:41:08', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '75fccedf-2465-44da-bc6a-d692da6738de'	System	21 Sep 2020 15:42:13
User entered 'No (N)'	System	21 Sep 2020 15:42:13

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:41:13', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '75fccedf-2465-44da-bc6a-d692da6738de'	System	21 Sep 2020 15:42:13
User entered 'None (1)'	System	21 Sep 2020 15:42:13

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:41:22', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '75fccedf-2465-44da-bc6a-d692da6738de'	System	21 Sep 2020 15:42:13
User entered '21 Sep 2020 10:41'	System	21 Sep 2020 15:42:13

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '21 Sep 2020 10:39'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '21 Sep 2020 13:09'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:07:50', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '45c2f707-b4eb-4d20-b61e-fd9541a3602c'	System	22 Sep 2020 01:08:58
User entered 'None (1)'	System	22 Sep 2020 01:08:58

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:07:57', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '45c2f707-b4eb-4d20-b61e-fd9541a3602c'	System	22 Sep 2020 01:08:58
User entered 'No (N)'	System	22 Sep 2020 01:08:58

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:08:23', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '45c2f707-b4eb-4d20-b61e-fd9541a3602c'	System	22 Sep 2020 01:08:58
User entered 'No (N)'	System	22 Sep 2020 01:08:58

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:08:46', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '45c2f707-b4eb-4d20-b61e-fd9541a3602c'	System	22 Sep 2020 01:08:58
User entered 'None (1)'	System	22 Sep 2020 01:08:58

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:08:53', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '45c2f707-b4eb-4d20-b61e-fd9541a3602c'	System	22 Sep 2020 01:08:58
User entered '21 Sep 2020 20:08'	System	22 Sep 2020 01:08:58

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '21 Sep 2020 14:04'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 2'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:22', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '460f410b-6699-4236-a6bc-692cb2182471'	System	22 Sep 2020 18:24:46
User entered 'None (1)'	System	22 Sep 2020 18:24:46

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:26', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '460f410b-6699-4236-a6bc-692cb2182471'	System	22 Sep 2020 18:24:46
User entered 'No (N)'	System	22 Sep 2020 18:24:46

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:30', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '460f410b-6699-4236-a6bc-692cb2182471'	System	22 Sep 2020 18:24:46
User entered 'No (N)'	System	22 Sep 2020 18:24:46

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:35', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '460f410b-6699-4236-a6bc-692cb2182471'	System	22 Sep 2020 18:24:46
User entered 'None (1)'	System	22 Sep 2020 18:24:46

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:39', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '460f410b-6699-4236-a6bc-692cb2182471'	System	22 Sep 2020 18:24:46
User entered '22 Sep 2020 13:24'	System	22 Sep 2020 18:24:46

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 3'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:03', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '2efd376b-4e9e-4301-831f-d35c5e2569f6'	System	24 Sep 2020 01:17:20
User entered 'None (1)'	System	24 Sep 2020 01:17:20

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:08', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '2efd376b-4e9e-4301-831f-d35c5e2569f6'	System	24 Sep 2020 01:17:20
User entered 'No (N)'	System	24 Sep 2020 01:17:20

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:10', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '2efd376b-4e9e-4301-831f-d35c5e2569f6'	System	24 Sep 2020 01:17:20
User entered 'No (N)'	System	24 Sep 2020 01:17:20

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:14', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '2efd376b-4e9e-4301-831f-d35c5e2569f6'	System	24 Sep 2020 01:17:20
User entered 'None (1)'	System	24 Sep 2020 01:17:20

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:17', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '2efd376b-4e9e-4301-831f-d35c5e2569f6'	System	24 Sep 2020 01:17:20
User entered '23 Sep 2020 20:17'	System	24 Sep 2020 01:17:20

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 4'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:05', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37796460-5dcb-462b-aa1e-6fa41087d644'	System	24 Sep 2020 17:36:24
User entered 'None (1)'	System	24 Sep 2020 17:36:24

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:08', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37796460-5dcb-462b-aa1e-6fa41087d644'	System	24 Sep 2020 17:36:24
User entered 'No (N)'	System	24 Sep 2020 17:36:24

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:13', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37796460-5dc6-462b-aa1e-6fa41087d644'	System	24 Sep 2020 17:36:24
User entered 'No (N)'	System	24 Sep 2020 17:36:24

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:16', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37796460-5dcb-462b-aa1e-6fa41087d644'	System	24 Sep 2020 17:36:24
User entered 'None (1)'	System	24 Sep 2020 17:36:24

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:20', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '37796460-5dcb-462b-aa1e-6fa41087d644'	System	24 Sep 2020 17:36:24
User entered '24 Sep 2020 12:36'	System	24 Sep 2020 17:36:24

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 5'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:39', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'de53a553-232f-4062-8979-58d975e6dd98'	System	25 Sep 2020 23:37:53
User entered 'None (1)'	System	25 Sep 2020 23:37:53

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:42', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'de53a553-232f-4062-8979-58d975e6dd98'	System	25 Sep 2020 23:37:53
User entered 'No (N)'	System	25 Sep 2020 23:37:53

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:44', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'de53a553-232f-4062-8979-58d975e6dd98'	System	25 Sep 2020 23:37:53
User entered 'No (N)'	System	25 Sep 2020 23:37:53

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:46', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'de53a553-232f-4062-8979-58d975e6dd98'	System	25 Sep 2020 23:37:53
User entered 'None (1)'	System	25 Sep 2020 23:37:53

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:49', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'de53a553-232f-4062-8979-58d975e6dd98'	System	25 Sep 2020 23:37:53
User entered '25 Sep 2020 18:37'	System	25 Sep 2020 23:37:53

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 6'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:00:51', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '5f4e37f2-e248-424b-96e9-547727225b22'	System	26 Sep 2020 17:01:35
User entered 'None (1)'	System	26 Sep 2020 17:01:35

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:00:54', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '5f4e37f2-e248-424b-96e9-547727225b22'	System	26 Sep 2020 17:01:35
User entered 'No (N)'	System	26 Sep 2020 17:01:35

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:00:56', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '5f4e37f2-e248-424b-96e9-547727225b22'	System	26 Sep 2020 17:01:35
User entered 'No (N)'	System	26 Sep 2020 17:01:35

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:00:59', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '5f4e37f2-e248-424b-96e9-547727225b22'	System	26 Sep 2020 17:01:35
User entered 'None (1)'	System	26 Sep 2020 17:01:35

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:01:03', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '5f4e37f2-e248-424b-96e9-547727225b22'	System	26 Sep 2020 17:01:35
User entered '26 Sep 2020 12:01'	System	26 Sep 2020 17:01:35

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 7'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:15:53', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bc4a108f-d475-4539-b5cd-2b94d9bb0e3d'	System	27 Sep 2020 17:16:09
User entered 'None (1)'	System	27 Sep 2020 17:16:09

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:15:56', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bc4a108f-d475-4539-b5cd-2b94d9bb0e3d'	System	27 Sep 2020 17:16:09
User entered 'No (N)'	System	27 Sep 2020 17:16:09

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:15:58', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bc4a108f-d475-4539-b5cd-2b94d9bb0e3d'	System	27 Sep 2020 17:16:09
User entered 'No (N)'	System	27 Sep 2020 17:16:09

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:16:02', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bc4a108f-d475-4539-b5cd-2b94d9bb0e3d'	System	27 Sep 2020 17:16:09
User entered 'None (1)'	System	27 Sep 2020 17:16:09

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:16:05', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'bc4a108f-d475-4539-b5cd-2b94d9bb0e3d'	System	27 Sep 2020 17:16:09
User entered '27 Sep 2020 12:16'	System	27 Sep 2020 17:16:09

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:42:10', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '00bffa71a-9132-432c-a07b-b94a11136037'	System	21 Sep 2020 15:42:39
User entered 'No interference with activity (1)'	System	21 Sep 2020 15:42:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:42:13', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '00bffa1a-9132-432c-a07b-b94a11136037'	System	21 Sep 2020 15:42:39
User entered 'None (0)'	System	21 Sep 2020 15:42:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:42:17', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '00bffa1a-9132-432c-a07b-b94a11136037'	System	21 Sep 2020 15:42:39
User entered 'None (0)'	System	21 Sep 2020 15:42:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:42:19', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '00bff71a-9132-432c-a07b-b94a11136037'	System	21 Sep 2020 15:42:39
User entered 'None (0)'	System	21 Sep 2020 15:42:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:42:22', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '00bff71a-9132-432c-a07b-b94a11136037'	System	21 Sep 2020 15:42:39
User entered 'None (0)'	System	21 Sep 2020 15:42:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:42:24', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '00bff71a-9132-432c-a07b-b94a11136037'	System	21 Sep 2020 15:42:39
User entered 'None (0)'	System	21 Sep 2020 15:42:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:42:28', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '00bff71a-9132-432c-a07b-b94a11136037'	System	21 Sep 2020 15:42:39
User entered 'No (N)'	System	21 Sep 2020 15:42:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T10:42:32', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '00bffa71a-9132-432c-a07b-b94a11136037'	System	21 Sep 2020 15:42:39
User entered '21 Sep 2020 10:42'	System	21 Sep 2020 15:42:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '21 Sep 2020 10:39'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '21 Sep 2020 13:09'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:08:58', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '646d4da6-b0c1-4178-947a-2c09e7647896'	System	22 Sep 2020 01:09:51
User entered 'None (0)'	System	22 Sep 2020 01:09:51

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:09:03', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '646d4da6-b0c1-4178-947a-2c09e7647896'	System	22 Sep 2020 01:09:51
User entered 'None (0)'	System	22 Sep 2020 01:09:51

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:09:08', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '646d4da6-b0c1-4178-947a-2c09e7647896'	System	22 Sep 2020 01:09:51
User entered 'None (0)'	System	22 Sep 2020 01:09:51

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:09:15', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '646d4da6-b0c1-4178-947a-2c09e7647896'	System	22 Sep 2020 01:09:51
User entered 'None (0)'	System	22 Sep 2020 01:09:51

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:09:18', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '646d4da6-b0c1-4178-947a-2c09e7647896'	System	22 Sep 2020 01:09:51
User entered 'None (0)'	System	22 Sep 2020 01:09:51

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:09:21', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '646d4da6-b0c1-4178-947a-2c09e7647896'	System	22 Sep 2020 01:09:51
User entered 'None (0)'	System	22 Sep 2020 01:09:51

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:09:43', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '646d4da6-b0c1-4178-947a-2c09e7647896'	System	22 Sep 2020 01:09:51
User entered 'No (N)'	System	22 Sep 2020 01:09:51

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-21T20:09:47', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '646d4da6-b0c1-4178-947a-2c09e7647896'	System	22 Sep 2020 01:09:51
User entered '21 Sep 2020 20:09'	System	22 Sep 2020 01:09:51

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '21 Sep 2020 14:04'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 2'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:44', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4935ee4a-b7dc-4228-9a41-a72e21eebd85'	System	22 Sep 2020 18:25:15
User entered 'None (0)'	System	22 Sep 2020 18:25:15

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:47', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4935ee4a-b7dc-4228-9a41-a72e21eebd85'	System	22 Sep 2020 18:25:15
User entered 'None (0)'	System	22 Sep 2020 18:25:15

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:49', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4935ee4a-b7dc-4228-9a41-a72e21eebd85'	System	22 Sep 2020 18:25:15
User entered 'None (0)'	System	22 Sep 2020 18:25:15

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:52', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4935ee4a-b7dc-4228-9a41-a72e21eebd85'	System	22 Sep 2020 18:25:15
User entered 'None (0)'	System	22 Sep 2020 18:25:15

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:54', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4935ee4a-b7dc-4228-9a41-a72e21eebd85'	System	22 Sep 2020 18:25:15
User entered 'None (0)'	System	22 Sep 2020 18:25:15

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:24:57', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4935ee4a-b7dc-4228-9a41-a72e21eebd85'	System	22 Sep 2020 18:25:15
User entered 'None (0)'	System	22 Sep 2020 18:25:15

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:25:07', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4935ee4a-b7dc-4228-9a41-a72e21eebd85'	System	22 Sep 2020 18:25:15
User entered 'No (N)'	System	22 Sep 2020 18:25:15

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-22T13:25:10', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '4935ee4a-b7dc-4228-9a41-a72e21eebd85'	System	22 Sep 2020 18:25:15
User entered '22 Sep 2020 13:25'	System	22 Sep 2020 18:25:15

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 3'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:22', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1a63fb7c-d310-4c5a-942d-b69ae9d59d8d'	System	24 Sep 2020 01:17:52
User entered 'None (0)'	System	24 Sep 2020 01:17:52

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:24', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1a63fb7c-d310-4c5a-942d-b69ae9d59d8d'	System	24 Sep 2020 01:17:52
User entered 'None (0)'	System	24 Sep 2020 01:17:52

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:26', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1a63fb7c-d310-4c5a-942d-b69ae9d59d8d'	System	24 Sep 2020 01:17:52
User entered 'None (0)'	System	24 Sep 2020 01:17:52

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:28', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1a63fb7c-d310-4c5a-942d-b69ae9d59d8d'	System	24 Sep 2020 01:17:52
User entered 'None (0)'	System	24 Sep 2020 01:17:52

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:30', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1a63fb7c-d310-4c5a-942d-b69ae9d59d8d'	System	24 Sep 2020 01:17:52
User entered 'None (0)'	System	24 Sep 2020 01:17:52

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:33', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1a63fb7c-d310-4c5a-942d-b69ae9d59d8d'	System	24 Sep 2020 01:17:52
User entered 'None (0)'	System	24 Sep 2020 01:17:52

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:35', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1a63fb7c-d310-4c5a-942d-b69ae9d59d8d'	System	24 Sep 2020 01:17:52
User entered 'No (N)'	System	24 Sep 2020 01:17:52

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-23T20:17:39', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1a63fb7c-d310-4c5a-942d-b69ae9d59d8d'	System	24 Sep 2020 01:17:52
User entered '23 Sep 2020 20:17'	System	24 Sep 2020 01:17:52

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 4'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:24', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'd49cb286-81e5-4f8b-afb0-93d02a151794'	System	24 Sep 2020 17:36:44
User entered 'None (0)'	System	24 Sep 2020 17:36:44

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:26', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'd49cb286-81e5-4f8b-afb0-93d02a151794'	System	24 Sep 2020 17:36:44
User entered 'None (0)'	System	24 Sep 2020 17:36:44

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:28', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'd49cb286-81e5-4f8b-afb0-93d02a151794'	System	24 Sep 2020 17:36:44
User entered 'None (0)'	System	24 Sep 2020 17:36:44

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:31', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'd49cb286-81e5-4f8b-afb0-93d02a151794'	System	24 Sep 2020 17:36:44
User entered 'None (0)'	System	24 Sep 2020 17:36:44

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:33', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'd49cb286-81e5-4f8b-afb0-93d02a151794'	System	24 Sep 2020 17:36:44
User entered 'None (0)'	System	24 Sep 2020 17:36:44

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:36', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'd49cb286-81e5-4f8b-afb0-93d02a151794'	System	24 Sep 2020 17:36:44
User entered 'None (0)'	System	24 Sep 2020 17:36:44

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:40', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'd49cb286-81e5-4f8b-afb0-93d02a151794'	System	24 Sep 2020 17:36:44
User entered 'No (N)'	System	24 Sep 2020 17:36:44

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-24T12:36:42', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'd49cb286-81e5-4f8b-afb0-93d02a151794'	System	24 Sep 2020 17:36:44
User entered '24 Sep 2020 12:36'	System	24 Sep 2020 17:36:44

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 5'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:54', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c7efea0b-5245-4eb2-bfb7-43da13dfb9c0'	System	25 Sep 2020 23:38:32
User entered 'None (0)'	System	25 Sep 2020 23:38:32

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:56', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c7efea0b-5245-4eb2-bfb7-43da13dfb9c0'	System	25 Sep 2020 23:38:32
User entered 'None (0)'	System	25 Sep 2020 23:38:32

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:37:58', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c7efea0b-5245-4eb2-bfb7-43da13dfb9c0'	System	25 Sep 2020 23:38:32
User entered 'None (0)'	System	25 Sep 2020 23:38:32

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:38:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c7efea0b-5245-4eb2-bfb7-43da13dfb9c0'	System	25 Sep 2020 23:38:32
User entered 'None (0)'	System	25 Sep 2020 23:38:32

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:38:03', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c7efea0b-5245-4eb2-bfb7-43da13dfb9c0'	System	25 Sep 2020 23:38:32
User entered 'None (0)'	System	25 Sep 2020 23:38:32

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:38:05', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c7efea0b-5245-4eb2-bfb7-43da13dfb9c0'	System	25 Sep 2020 23:38:32
User entered 'None (0)'	System	25 Sep 2020 23:38:32

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:38:24', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c7efea0b-5245-4eb2-bfb7-43da13dfb9c0'	System	25 Sep 2020 23:38:32
User entered 'No (N)'	System	25 Sep 2020 23:38:32

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-25T18:38:28', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'c7efea0b-5245-4eb2-bfb7-43da13dfb9c0'	System	25 Sep 2020 23:38:32
User entered '25 Sep 2020 18:38'	System	25 Sep 2020 23:38:32

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 6'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:01:22', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c076269-a122-4772-a963-f110b6cfb10a'	System	26 Sep 2020 17:02:14
User entered 'None (0)'	System	26 Sep 2020 17:02:14

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:01:25', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c076269-a122-4772-a963-f110b6cfb10a'	System	26 Sep 2020 17:02:14
User entered 'None (0)'	System	26 Sep 2020 17:02:14

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:01:27', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c076269-a122-4772-a963-f110b6cfb10a'	System	26 Sep 2020 17:02:14
User entered 'None (0)'	System	26 Sep 2020 17:02:14

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:01:29', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c076269-a122-4772-a963-f110b6cfb10a'	System	26 Sep 2020 17:02:14
User entered 'None (0)'	System	26 Sep 2020 17:02:14

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:01:31', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c076269-a122-4772-a963-f110b6cfb10a'	System	26 Sep 2020 17:02:14
User entered 'None (0)'	System	26 Sep 2020 17:02:14

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:01:34', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c076269-a122-4772-a963-f110b6cfb10a'	System	26 Sep 2020 17:02:14
User entered 'None (0)'	System	26 Sep 2020 17:02:14

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:01:40', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c076269-a122-4772-a963-f110b6cfb10a'	System	26 Sep 2020 17:02:14
User entered 'No (N)'	System	26 Sep 2020 17:02:14

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-26T12:01:42', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '1c076269-a122-4772-a963-f110b6cfb10a'	System	26 Sep 2020 17:02:14
User entered '26 Sep 2020 12:01'	System	26 Sep 2020 17:02:14

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
Data entry locked.	System	21 Sep 2020 15:24:41
User entered 'Day 7'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:16:12', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '21901771-f7f7-4640-8b28-f82da09d5991'	System	27 Sep 2020 17:16:39
User entered 'None (0)'	System	27 Sep 2020 17:16:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:16:15', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '21901771-f7f7-4640-8b28-f82da09d5991'	System	27 Sep 2020 17:16:39
User entered 'None (0)'	System	27 Sep 2020 17:16:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:16:17', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '21901771-f7f7-4640-8b28-f82da09d5991'	System	27 Sep 2020 17:16:39
User entered 'None (0)'	System	27 Sep 2020 17:16:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:16:19', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '21901771-f7f7-4640-8b28-f82da09d5991'	System	27 Sep 2020 17:16:39
User entered 'None (0)'	System	27 Sep 2020 17:16:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:16:23', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '21901771-f7f7-4640-8b28-f82da09d5991'	System	27 Sep 2020 17:16:39
User entered 'None (0)'	System	27 Sep 2020 17:16:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:16:26', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '21901771-f7f7-4640-8b28-f82da09d5991'	System	27 Sep 2020 17:16:39
User entered 'None (0)'	System	27 Sep 2020 17:16:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

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 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:16:31', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '21901771-f7f7-4640-8b28-f82da09d5991'	System	27 Sep 2020 17:16:39
User entered 'No (N)'	System	27 Sep 2020 17:16:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61dc2cac435a5dd3)', Time: '2020-09-27T12:16:34', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '21901771-f7f7-4640-8b28-f82da09d5991'	System	27 Sep 2020 17:16:39
User entered '27 Sep 2020 12:16'	System	27 Sep 2020 17:16:39

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:24:41

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:18:58
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:25:25
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:14:56

US3752025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:25:25
User entered '28 Sep 2020'	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:14:56

US3752025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:25:25
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:14:56

US3752025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:25:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:14:56

US3752025

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
Query 'Please complete SCD39 eCRF page' canceled (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:25:58
User opened query 'Please complete SCD39 eCRF page' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 18:20:25
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:19:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:24:28

US3752025

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User entered 'I'	System	06 Oct 2020 12:24:28

US3752025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:37:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:24:45

US3752025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:37:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:24:45

US3752025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:37:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:24:45

US3752025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:37:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:24:45

US3752025

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:37:43
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:36

US3752025

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User entered 'I'	System	12 Oct 2020 18:47:36

US3752025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:37:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:45

US3752025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:37:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '12 Oct 2020'	(b) (4) Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:45

US3752025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:37:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:45

US3752025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:37:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:45

US3752025

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:38:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:48

US3752025

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User entered 'I'	System	12 Oct 2020 18:47:48

US3752025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:08:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:44

US3752025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:08:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '19 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:07:35
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 16:01:44

US3752025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[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 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:08:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:44

US3752025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'VISIT3'	System	19 Oct 2020 16:01:44

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Oct 2020 16:07:49
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Oct 2020 16:07:49
User entered '19 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:07:49
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 16:07:35
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10:10'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '19 Oct 2020 10:10'	System	19 Oct 2020 16:07:49
User entered '16 Oct 2020 10:10'	System	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '99'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'bpm'	System	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'breaths/min'	System	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '122'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'mmHg'	System	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '82'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'mmHg'	System	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36

US3752025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:35

US3752025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Oct 2020 16:07:55
User entered '19 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:07:55
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 16:07:35
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 16:02:35

US3752025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:54

US3752025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Oct 2020 16:08:03
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Oct 2020 16:08:03
User entered '19 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:08:03
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 16:07:35
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 16:02:54

US3752025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '10:15'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:54

US3752025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered '19 Oct 2020 10:15'	System	19 Oct 2020 16:08:03
User entered '16 Oct 2020 10:15'	System	19 Oct 2020 16:02:54

US3752025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:02:58

US3752025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:36
User entered 'I'	System	19 Oct 2020 16:02:58

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 64'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Have you been exposed to someone with 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Please 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Please 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
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US3752025

Folder: Safety Follow Up Diary (1)

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[Please 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 13:42:04
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US3752025

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
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US3752025

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 71'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Have you been exposed to someone with 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 13:42:04
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US3752025

Folder: Safety Follow Up Diary (1)

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[Please 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)
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US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3752025

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Please 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
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US3752025

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[Please 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 13:42:04
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US3752025

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[Date and time of submission](#)

Audit	User	Time (GMT)
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 78'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Have you been exposed to someone with 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Please 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)
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US3752025

Folder: Safety Follow Up Diary (1)

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[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
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US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Please 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Please 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 92'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Have you been exposed to someone with 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Please 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Please 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

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[Please 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3752025

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3752025

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered 'Day 99'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Have you been exposed to someone with 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Please 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)
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Please 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Please 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 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 18:05:20

US3752025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:11:07
Data entry locked.	System	10 Aug 2020 18:05:20
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 18:05:20

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 (7f9448633fe4318e)', Time: '2021-02-13T09:52:25', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '60f886bc-ec12-4496-ad0c-48da7caa46b2'	System	13 Feb 2021 15:53:04
User entered 'Yes (Y)'	System	13 Feb 2021 15:53:04

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Have you been exposed to someone with 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 (7f9448633fe4318e)', Time: '2021-02-13T09:52:32', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '60f886bc-ec12-4496-ad0c-48da7caa46b2'	System	13 Feb 2021 15:53:04
User entered 'No (N)'	System	13 Feb 2021 15:53:04

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 (7f9448633fe4318e)', Time: '2021-02-13T09:52:38', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '60f886bc-ec12-4496-ad0c-48da7caa46b2'	System	13 Feb 2021 15:53:04
User entered 'No (N)'	System	13 Feb 2021 15:53:04

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 (7f9448633fe4318e)', Time: '2021-02-13T09:52:48', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '60f886bc-ec12-4496-ad0c-48da7caa46b2'	System	13 Feb 2021 15:53:04
User entered 'No (N)'	System	13 Feb 2021 15:53:04

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f9448633fe4318e)', Time: '2021-02-13T09:53:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '60f886bc-ec12-4496-ad0c-48da7caa46b2'	System	13 Feb 2021 15:53:04
User entered '13 Feb 2021 09:53:00'	System	13 Feb 2021 15:53:04

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 (7f9448633fe4318e)', Time: '2021-02-17T00:01:43', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b3132c5a-ed0f-47d5-9a3e-e076e9712316'	System	17 Feb 2021 06:02:08
User entered 'No (N)'	System	17 Feb 2021 06:02:08

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Have you been exposed to someone with 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 (7f9448633fe4318e)', Time: '2021-02-17T00:01:54', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b3132c5a-ed0f-47d5-9a3e-e076e9712316'	System	17 Feb 2021 06:02:08
User entered 'No (N)'	System	17 Feb 2021 06:02:08

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f9448633fe4318e)', Time: '2021-02-17T00:02:03', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'b3132c5a-ed0f-47d5-9a3e-e076e9712316'	System	17 Feb 2021 06:02:08
User entered '17 Feb 2021 00:02:03'	System	17 Feb 2021 06:02:08

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 (7f9448633fe4318e)', Time: '2021-02-24T13:00:12-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '10dae493-5cca-4a33-802a-5e622f238334' User entered 'No (N)'	System	24 Feb 2021 19:01:05
	System	24 Feb 2021 19:01:05

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Have you been exposed to someone with 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 (7f9448633fe4318e)', Time: '2021-02-24T13:00:26-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '10dae493-5cca-4a33-802a-5e622f238334'	System	24 Feb 2021 19:01:05
User entered 'Yes (Y)'	System	24 Feb 2021 19:01:05

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Please 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 (7f9448633fe4318e)', Time: '2021-02-24T13:00:45-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '10dae493-5cca-4a33-802a-5e622f238334'	System	24 Feb 2021 19:01:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Feb 2021 19:01:05

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f9448633fe4318e)', Time: '2021-02-24T13:00:51-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '10dae493-5cca-4a33-802a-5e622f238334' User entered '24 Feb 2021 13:00:51'	System	24 Feb 2021 19:01:05
	System	24 Feb 2021 19:01:05

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 (7f9448633fe4318e)', Time: '2021-03-07T08:42:30-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'fba7b77e-a4a3-42d5-8cd1-c11d7d76ef1b'	System	07 Mar 2021 14:42:53
User entered 'No (N)'	System	07 Mar 2021 14:42:53

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

Have you been exposed to someone with 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 (7f9448633fe4318e)', Time: '2021-03-07T08:42:41-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'fba7b77e-a4a3-42d5-8cd1-c11d7d76ef1b'	System	07 Mar 2021 14:42:53
User entered 'No (N)'	System	07 Mar 2021 14:42:53

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f9448633fe4318e)', Time: '2021-03-07T08:42:49-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: 'fba7b77e-a4a3-42d5-8cd1-c11d7d76ef1b' User entered '07 Mar 2021 08:42:49'	System	07 Mar 2021 14:42:53
	System	07 Mar 2021 14:42:53

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[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 (7f9448633fe4318e)', Time: '2021-03-12T12:49:52-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '92421657-a6bf-48d9-b076-4106650b0f97'	System	12 Mar 2021 18:50:07
User entered 'No (N)'	System	12 Mar 2021 18:50:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Have you been exposed to someone with 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 (7f9448633fe4318e)', Time: '2021-03-12T12:49:58-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '92421657-a6bf-48d9-b076-4106650b0f97'	System	12 Mar 2021 18:50:07
User entered 'No (N)'	System	12 Mar 2021 18:50:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f9448633fe4318e)', Time: '2021-03-12T12:50:03-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '92421657-a6bf-48d9-b076-4106650b0f97'	System	12 Mar 2021 18:50:07
User entered '12 Mar 2021 12:50:03'	System	12 Mar 2021 18:50:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 17:11:07

US3752025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:41:55

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 13:42:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f9448633fe4318e)', Time: '2021-03-07T08:42:06-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '6f1aa8db-bdab-4fe4-8965-06a483940875'	System	07 Mar 2021 14:42:19
User entered 'No (N)'	System	07 Mar 2021 14:42:19

US3752025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:41:55

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:42:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f9448633fe4318e)', Time: '2021-03-07T08:42:15-06:00', User OID: 'PatientReportedOutcome (US3752025)', ODM File OID: '6f1aa8db-bdab-4fe4-8965-06a483940875' User entered '07 Mar 2021 08:42:15'	System	07 Mar 2021 14:42:19
	System	07 Mar 2021 14:42:19

US3752025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 18:44:35
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:39:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:19:39

US3752025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:39:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:19:39

US3752025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 18:44:38
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:39:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:19:39

US3752025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:09:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 18:44:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 18:39:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:19:39

US3752025

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:10:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:19:43

US3752025

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:47:27
User entered 'I'	System	16 Nov 2020 18:19:43

US3752025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:38:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	20 Jan 2021 17:24:00

US3752025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:38:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	20 Jan 2021 17:24:00

US3752025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:38:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	20 Jan 2021 17:24:00
	(b) (4)	

US3752025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:38:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	20 Jan 2021 17:24:00
	(b) (4)	

US3752025

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:16:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	20 Jan 2021 17:24:03

US3752025

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
User entered 'I'	System	20 Jan 2021 17:24:03

US3752025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:11:22
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	20 Jan 2021 17:24:11

US3752025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-FEB-2021 is reported under Participant Decision Visit/OL-D1 in PPD portal; however, swab sample for 12-FEB-2021 is missing in EDC. Kindly review if the swab sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 10:17:27
	(b) (4), (b) (6)	01 Mar 2021 21:11:22
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-FEB-2021 is reported under Participant Decision Visit/OL-D1 in PPD portal; however, swab sample for 12-FEB-2021 is missing in EDC. Kindly review if the swab sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF under Participant Decision Visit / OL-D1 eCRF, else clarify. ' answered with 'UPDATED' (Site from DM).	Amanda Horn (b) (4)	01 Mar 2021 19:38:17
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-FEB-2021 is reported under Participant Decision Visit/OL-D1 in PPD portal; however, swab sample for 12-FEB-2021 is missing in EDC. Kindly review if the swab sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 11:04:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
	(b) (4)	
User entered '19 Jan 2021'	Amanda Horn (b) (4)	20 Jan 2021 17:24:11
	(b) (4)	

US3752025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:11:22
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	20 Jan 2021 17:24:11

US3752025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:11:22
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	20 Jan 2021 17:24:11

US3752025

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:11:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:51
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	20 Jan 2021 17:24:14

US3752025

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
User entered 'I'	System	20 Jan 2021 17:24:14

US3752025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:11:43
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3752025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:11:43
User entered '18 Feb 2021'	Amanda Horn (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3752025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:11:43
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3752025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:11:43
User entered empty.	Amanda Horn (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3752025

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:11:52
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	24 Feb 2021 18:36:04

US3752025

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:49
User entered 'I'	System	24 Feb 2021 18:36:04

US3752025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:19
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:00:57

US3752025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:19
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 09 Mar 2021,However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.	(b) (4), (b) (6)	01 Apr 2021 13:46:54
' (Site from DM).		
Query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 09 Mar 2021,However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:56:06
' answered with 'Corrected with same date' (Site from DM).		
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 09 Mar 2021,However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.	(b) (4), (b) (6)	29 Mar 2021 11:31:21
' (Site from DM).		
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:12:20
User entered '09 Mar 2021'	Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:00:57

US3752025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:19
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Clinic (Clinic)'	Haylee Rowe (b) (4)	09 Mar 2021 20:00:57

US3752025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
User entered 'VISIT4'	System	09 Mar 2021 20:00:57

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:32
User signature succeeded.	Priyantha Wijewardane	29 Mar 2021 16:33:33
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:32
User signature succeeded.	Priyantha Wijewardane	29 Mar 2021 16:33:33
User entered '09 Mar 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:32
User signature succeeded.	Priyantha Wijewardane	29 Mar 2021 16:33:33
User entered '11:20'	(b) (4)	
	Haylee Rowe (b) (4)	29 Mar 2021 15:47:37
	(b) (4)	

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
User entered '09 Mar 2021 11:20'	System	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:32
User signature succeeded.	Priyantha Wijewardane	29 Mar 2021 16:33:33
User entered '98.4' F	(b) (4) Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:32
User signature succeeded.	Priyantha Wijewardane	29 Mar 2021 16:33:33
User entered 'Oral (Oral)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:32
User signature succeeded.	Priyantha Wijewardane	29 Mar 2021 16:33:33
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	29 Mar 2021 15:47:37
	(b) (4)	

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:32
User signature succeeded.	Priyantha Wijewardane	29 Mar 2021 16:33:33
User entered '99'	(b) (4) Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
User entered 'bpm'	System	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:32
User signature succeeded.	Priyantha Wijewardane	29 Mar 2021 16:33:33
User entered '18'	(b) (4) Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
User entered 'breaths/min'	System	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:32
User signature succeeded.	Priyantha Wijewardane	29 Mar 2021 16:33:33
User entered '116'	(b) (4) Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
User entered 'mmHg'	System	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:32
User signature succeeded.	Priyantha Wijewardane	29 Mar 2021 16:33:33
User entered '78'	(b) (4) Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
User entered 'mmHg'	System	29 Mar 2021 15:47:37

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59

US3752025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59

US3752025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:01:05

US3752025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '09 Mar 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:01:05

US3752025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:01:22

US3752025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '09 Mar 2021'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:01:22
	(b) (4)	

US3752025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '11:30'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:01:22

US3752025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
User entered '09 Mar 2021 11:30'	System	09 Mar 2021 20:01:22

US3752025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:01:26

US3752025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:52:59
User entered 'I'	System	09 Mar 2021 20:01:26

US3752025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	19 Apr 2021 19:50:00
	(b) (4)	

US3752025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
	(b) (4)	
User entered '19 Apr 2021'	Timothy Campbell (b) (4)	19 Apr 2021 19:50:00
	(b) (4)	

US3752025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Timothy Campbell (b) (4)	19 Apr 2021 19:50:00
	(b) (4)	

US3752025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
	(b) (4)	
User entered empty.	Timothy Campbell (b) (4)	19 Apr 2021 19:50:00
	(b) (4)	

US3752025

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	19 Apr 2021 19:50:05
	(b) (4)	

US3752025

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 19:50:05

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:55

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:09:25
User entered '9 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:51:48

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:55

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:09:26
User entered '13:00'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:51:48

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:55

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:17
User entered '9 Oct 2020 13:00'	System	12 Oct 2020 18:51:48

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:55

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:09:28
User entered 'Safety Call (Safety Call)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:51:48

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:55

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:09:37
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:51:48

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
Query 'Per source, Day2=10 Oct2020, EDC= 20 Oct 2020. Please review and clarify.' canceled (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:23:04
User opened query 'Per source, Day2=10 Oct2020, EDC= 20 Oct 2020. Please review and clarify.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:17:33
User closed query 'persource, subject c/o symptoms starting on 2Oct2020-please reconcile' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Query 'persource, subject c/o symptoms starting on 2Oct2020-please reconcile' answered with 'done' (Site from CRA).	(b) (4)	
	Jamie Pettus (b) (4)	01 Feb 2021 14:43:04
	(b) (4)	
User opened query 'persource, subject c/o symptoms starting on 2Oct2020-please reconcile' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 14:48:48
User entered 'Day 2 (Day 2)'	Amanda Horn (b) (4)	12 Oct 2020 18:52:56
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:40:41
User closed query 'Per source, Day2=10 Oct2020, EDC= 20 Oct 2020. Please review and clarify' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 15:40:37
Query 'Per source, Day2=10 Oct2020, EDC= 20 Oct 2020. Please review and clarify' answered with 'CORRECTED' (Site from CRA).	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:36:02
Signature has been broken.	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:35:44
User entered '10 Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:35:44
User opened query 'Per source, Day2=10 Oct2020, EDC= 20 Oct 2020. Please review and clarify' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:23:16
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:02:47
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 14:42:57
User entered '20 Oct 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 14:42:57
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:10:12
User entered '10 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:23
User entered '98'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User entered '%'	System	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Correct temp to 97.9--delete leading 0.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:24:13
Query 'Correct temp to 97.9--delete leading 0.' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:11:27
User entered '97.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:11:20
User opened query 'Correct temp to 97.9--delete leading 0.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:10:55
User entered '097.9' F	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:36
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:34
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:39
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:40
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:42
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:43
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:48
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:50
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:52
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:55
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:57
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:11:58
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:12:03
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:12:04
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:12:06
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:12:08
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 3 (Day 3)'	(b) (4) Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:32
User entered '11 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:33
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:35
User entered '96'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User entered '%'	System	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:36
User entered '97.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:11:46
User entered '097.8' F	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:43
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:45
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:46
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:49
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:51
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:53
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:54
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:57
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:13:59
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:14:01
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:14:06
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:14:08
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:14:09
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:14:11
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:14:13
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:14:15
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 4 (Day 4)'	(b) (4) Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:14:43
User entered '12 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:26:54
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:26:55
User entered missing code ND - Not Done.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User entered '%'	System	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:26:57
User entered missing code ND - Not Done.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:28
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:30
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:33
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:35
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:36
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:38
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:41
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:42
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:44
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:30:30
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:30:35
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:30:36
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:30:38
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:30:40
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:30:43
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:30:44
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:41
User entered '9 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:54

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[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 19:25:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:43
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:54

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[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 19:25:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:45
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:54

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:47
User entered '9 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:54

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:48
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:54

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:54

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[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 19:25:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:52
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:54

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:57
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:54

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:59
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:56:54

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:33
User entered '0'	System	12 Oct 2020 18:56:54

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:41:55

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:50:24
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:08:05

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:55

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:34
User entered '12 Nov 2020'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:20:36

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:55

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:35
User entered '11:30'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:20:36

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:55

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:54
User entered '12 Nov 2020 11:30'	System	12 Nov 2020 22:20:36

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:55

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:36
User entered 'Safety Call (Safety Call)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:20:36

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:55

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:25:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:38
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:20:36

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:16
User entered '8 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:29:05
User entered '08 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:20
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:23
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:39
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:53
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:56
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:58
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:00
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:02
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:04
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:48
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:07
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:09
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:10
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:13
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:15
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:22
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:37
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:39
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:54
User entered '9 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:55
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:34:22
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	17 Nov 2020 15:34:22
User entered empty.	System	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:36:20
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:37:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:25
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:29
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:32
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:11
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:37
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:26
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:28
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:37
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:53
User entered '10 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:55
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:14
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:34:22
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	17 Nov 2020 15:34:22
User entered empty.	System	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:18
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:36:20
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:37:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:47
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:32
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:56
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:57
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:34:02
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:34:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:34:14
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:34:11
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:34:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:34:29
User entered '11 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:34:32
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:34:36
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:34:22
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	17 Nov 2020 15:34:22
User entered empty.	System	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:23
Query 'Source says 98.3. Please correct' canceled (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:35:21
User opened query 'Source says 98.3. Please correct' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:35:05
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:36:20
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:25
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:37:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:29
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:35
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:37
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:44
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:45
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:47
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:36:04
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:36:06
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:36:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:36:10
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:36:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:38:38
User entered '12 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:38:41
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:38:44
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:34:22
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	17 Nov 2020 15:34:22
User entered empty.	System	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:38:46
User entered '98.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:36:20
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:37:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:29
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:31
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:10
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:12
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:14
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:35
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:39:58
User entered '13 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:00
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:03
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:34:22
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	17 Nov 2020 15:34:22
User entered empty.	System	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:06
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:36:20
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:37:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:22
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:25
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:29
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:31
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:38
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:40:40
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:42:06
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:42:22
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:42:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:42:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:42:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:42:56
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:42:51
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:42:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:43:07
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:19
User entered '14 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:21
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:34:22
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	17 Nov 2020 15:34:22
User entered empty.	System	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:36:20
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:44
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:37:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:46
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:48
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:52
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:03
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:06
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:08
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:25
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:40
User entered '15 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:42
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:34:22
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	17 Nov 2020 15:34:22
User entered empty.	System	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:36:20
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:16
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:37:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:22
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:29
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:31
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:04
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:09
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:11
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:56
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:48:10
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:48:12
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:04
User entered '95' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:34:22
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	17 Nov 2020 15:34:22
User entered empty.	System	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:07
User entered '97.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:36:20
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:48
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:37:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:48
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:51
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:41:13
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:29:22
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:17
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:38
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	17 Nov 2020 15:48:14
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:44
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:29:26
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:32:57
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:33:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:33:02
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:33:04
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:33:06
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:48:14
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:57:46
User entered '17 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:57:48
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:57:50
User entered '93' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	17 Nov 2020 22:51:54
User entered empty.	System	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:57:59
User entered '97.7' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:58:17
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:58:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:58:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:58:30
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:58:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:58:35
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:58:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:58:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:58:52
User entered 'Severe (Severe)' reason for change:	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:58:54
User entered 'Severe (Severe)' reason for change:	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:02
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:06
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:07
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:09
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:10
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:13
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 22:51:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 11 (Day 11)'	(b) (4) Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:24
User entered '18 Nov 2020'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:40
User entered '97'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:41
User entered '97.7' F	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:43
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:45
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:46
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:59:49
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:00
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:02
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:06
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:07
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:21
User entered 'Severe (Severe)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:22
User entered 'Severe (Severe)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:24
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:25
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:29
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:30
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:31
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:00:32
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 12 (Day 12)'	(b) (4) Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:02
User entered '19 Nov 2020'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:04
User entered '0'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:19
User entered '97'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:21
User entered '96.7' F	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:34
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:35
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:37
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:38
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:49
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:51
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:01:52
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:02:19
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:02:20
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:02:22
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:07:48
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:07:49
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:07:51
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:08:10
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:08:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:08:13
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 13 (Day 13)'	(b) (4) Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:08:39
User entered '20 Nov 2020'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:08:40
User entered '0'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:08:42
User entered '95'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:08:44
User entered '97.7' F	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:15
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:16
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:18
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:19
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:27
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:28
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:30
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:31
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:46
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:48
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:49
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:53
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:54
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:55
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:57
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:09:59
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 14 (Day 14)'	(b) (4) Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:11
User entered '21 Nov 2020'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:13
User entered '0'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:23
User entered '95'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:24
User entered '97.0' F	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:34
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:35
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:37
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:38
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:52
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:53
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:55
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:10:56
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:14:26
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:14:28
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:14:29
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:14:31
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:14:34
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:14:37
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:14:38
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:14:40
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 15 (Day 15)'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:14:51
User entered '22 Nov 2020'	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:14:53
User entered '0'	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:09
User entered '94' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	23 Nov 2020 18:56:33
User entered empty.	System	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:11
User entered '97.8' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:22
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:27
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:38
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:42
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:53
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:56
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:15:59
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:00
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:02
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:03
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:04
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 16 (Day 16)'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:12
User entered '23 Nov 2020'	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:14
User entered '0'	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:26
User entered '95' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	23 Nov 2020 18:56:33
User entered empty.	System	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:24
User entered '96.5' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:35
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:54
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:55
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:57
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:16:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:17:10
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:17:11
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:17:13
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:17:14
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:17:15
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:17:18
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:17:19
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:17:21
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 17 (Day 17)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:21
User entered '24 Nov 2020'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:23
User entered '0'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:26
User entered '96'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:29
User entered '98.1' F	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:36
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:37
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:39
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:42
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:44
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:52
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:54
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:52:56
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:05
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:08
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:09
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:15
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:16
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:18
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:21
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:23
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 18 (Day 18)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:43
User entered '25 Nov 2020'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:45
User entered '0'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:47
User entered '94'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:50
User entered '98.2' F	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:54
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:53:59
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:06
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:10
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:13
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:16
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:19
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:22
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:26
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:31
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:40
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:44
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:50
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:52
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:54:57
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:00
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	25 Nov 2020 22:02:24

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 19 (Day 19)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:11
User entered '26 Nov 2020'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:13
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:15
User entered '96'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:19
User entered '97.0' F	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:27
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:33
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:36
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:40
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:45
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:51
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:56
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:55:58
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:15
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:19
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:23
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:27
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:30
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:32
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:33
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 20 (Day 20)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:46
User entered '27 Nov 2020'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:48
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:51
User entered '96'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:54
User entered '98.1' F	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:56:58
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:00
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:04
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:07
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:11
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:15
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:18
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:20
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:25
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:26
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:29
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:30
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:34
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:35
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:38
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:40
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 14:58:52

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User closed query 'per CDM RQ: response noted, please clarify and/or reconcile symptom days for Nov. 26-30, as there are repeating day 19s and day 20s' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 20:11:09
User signature succeeded.	Priyantha Wijewardane	23 Mar 2021 23:09:26
Query 'per CDM RQ: response noted, please clarify and/or reconcile symptom days for Nov. 26-30, as there are repeating day 19s and day 20s' answered with 'CORRECTED' (Site from DM).	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	23 Mar 2021 00:07:42
	(b) (4)	
User entered 'Day 21 (Day 21)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Mar 2021 00:06:43
User opened query 'per CDM RQ: response noted, please clarify and/or reconcile symptom days for Nov. 26-30, as there are repeating day 19s and day 20s' (Site from DM).	(b) (4)	
User closed query 'Per CDM: Per sponsor review, please confirm Symptom Day as Day 19 is also recorded as 26Nov2020.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 21:08:29
Query 'Per CDM: Per sponsor review, please confirm Symptom Day as Day 19 is also recorded as 26Nov2020.' answered with 'data verified' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 21:08:29
User opened query 'Per CDM: Per sponsor review, please confirm Symptom Day as Day 19 is also recorded as 26Nov2020.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 20:44:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 19 (Day 19)'	(b) (4)	
	Amanda Horn (b) (4)	30 Nov 2020 15:00:19
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:53
User entered '28 Nov 2020'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:57
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:57:58
User entered '97'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:00
User entered '97.2' F	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:19
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:21
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:23
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:25
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:27
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:30
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:32
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:34
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:11
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:13
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:38
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:39
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:41
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:43
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:46
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:48
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User closed query ' per CDM RQ: response noted, please clarify and/or reconcile symptom days for Nov. 26-30, as there are repeating day 19s and day 20s' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 20:11:17
User signature succeeded.	Priyantha Wijewardane	23 Mar 2021 23:09:26
Query ' per CDM RQ: response noted, please clarify and/or reconcile symptom days for Nov. 26-30, as there are repeating day 19s and day 20s' answered with 'CORRECTED' (Site from DM).	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	23 Mar 2021 00:08:07
	(b) (4)	
User entered 'Day 22 (Day 22)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Mar 2021 00:06:43
User opened query ' per CDM RQ: response noted, please clarify and/or reconcile symptom days for Nov. 26-30, as there are repeating day 19s and day 20s' (Site from DM).	(b) (4)	
User closed query 'Per CDM: Per sponsor review, please confirm Symptom Day as Day 20 is also recorded as 27Nov20. Please adjust further entries as necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 21:08:49
Query 'Per CDM: Per sponsor review, please confirm Symptom Day as Day 20 is also recorded as 27Nov20. Please adjust further entries as necessary. Thank you.' answered with 'data verified' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 21:08:49
User opened query 'Per CDM: Per sponsor review, please confirm Symptom Day as Day 20 is also recorded as 27Nov20. Please adjust further entries as necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 20:45:10
User signature succeeded.	(b) (4), (b) (6)	16 Mar 2021 20:05:22
User entered 'Day 20 (Day 20)'	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
	Amanda Horn (b) (4)	30 Nov 2020 15:00:19
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:01
User entered '29 Nov 2020'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:03
User entered '0'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:06
User entered '98'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:08
User entered '98.0' F	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:22
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:24
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:26
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:28
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:31
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:33
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:35
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:36
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:15
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:17
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:39
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:41
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:43
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:45
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:47
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:59:49
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 15:00:19

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User signature succeeded.	Priyantha Wijewardane	23 Mar 2021 23:09:26
Signature has been broken.	(b) (4)	23 Mar 2021 00:06:43
User entered 'Day 23 (Day 23)' reason for change:	Amanda Horn (b) (4)	23 Mar 2021 00:06:43
Data Entry Error	(b) (4)	23 Mar 2021 00:06:43
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Day 21 (Day 21)'	(b) (4)	30 Nov 2020 22:24:54
	Amanda Horn (b) (4)	
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '30 Nov 2020'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '99'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
User entered '%'	System	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '98.3' F	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Mild (Mild)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Mild (Mild)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 09:41:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:02
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'None (None)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:24:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Query 'Per ETRTR: Date is still as 10Nov20. Please update to 09Nov20 if applicable, thanks.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:43:07
User opened query 'Per ETRTR: Date is still as 10Nov20. Please update to 09Nov20 if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:41:29
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:18:27
DataPoint Un-verified.	Amanda Horn (b) (4)	23 Nov 2020 19:05:26
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) Amanda Horn (b) (4)	23 Nov 2020 19:05:26
User closed query 'Source says date of covid test was 09NOV2020. Is this correct? If so, please update EDC.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:34:43
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:34:41
Query 'Source says date of covid test was 09NOV2020. Is this correct? If so, please update EDC.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 19:22:46
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:22:40
User opened query 'Source says date of covid test was 09NOV2020. Is this correct? If so, please update EDC.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:39:11
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[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 19:26:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:39:16
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[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 19:26:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
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) (4), (b) (6)	17 Nov 2020 15:58:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:39:17
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 'SUBJECT TESTED POSITIVE FOR FOR SARS-CoV-2 BY RT-PCR' (Site from System).	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:26:02
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	12 Nov 2020 22:25:20
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:08
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 11:07:49
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 COVID Diagnostic Test was performed while subject was in hospital for associated SAE of COVID positive plus hypotension. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	11 Mar 2021 17:46:40
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 19:07:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:18:35
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 19:05:26
User entered '10 Nov 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 19:05:26
User closed query 'Source says date of covid test was 09NOV2020. Is this correct? If so, please update EDC' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 16:59:23
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:59:21
Query 'Source says date of covid test was 09NOV2020. Is this correct? If so, please update EDC' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 16:52:24
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:52:17
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 16:52:17

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Source says date of covid test was 09NOV2020. Is this correct? If so, please update EDC' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 16:00:50
User closed query 'Please confirm if date is correct. update EDC as appropriate' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 15:36:53
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:51
Query 'Please confirm if date is correct. update EDC as appropriate' answered with 'DATE IS CORRECT' (Site from CRA).	Amanda Horn (b) (4)	17 Nov 2020 22:53:15
User opened query 'Please confirm if date is correct. update EDC as appropriate' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:51:38
User entered '10 Nov 2020'	Amanda Horn (b) (4)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:39:22
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:39:24
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[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 19:26:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:39:26
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:39:28
User entered 'BHMC NORTH LITTLE ROCK 3333 Springhill Dr. North Little Rock AR 72114'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:39:30
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:41:55

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:08
User entered 'I'	System	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:37
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

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 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:39
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:57
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:59
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

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 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:41:01
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:01:02
User closed query 'Please verify as symptom log notes first O2 meeting this criteria was on 10Nov2020 and it was ongoing as of last entry on 17Nov20' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:55:35
Query 'Please verify as symptom log notes first O2 meeting this criteria was on 10Nov2020 and it was ongoing as of last entry on 17Nov20' answered with 'changed' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:34:24
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:34:12
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:34:12
User opened query 'Please verify as symptom log notes first O2 meeting this criteria was on 10Nov2020 and it was ongoing as of last entry on 17Nov20' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:44:16
User closed query 'Should start/stop date be 09NOV2020? Please correct in EDC' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:40:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:40:16
Query 'Should start/stop date be 09NOV2020? Please correct in EDC' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 19:23:30
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:23:17
User opened query 'Should start/stop date be 09NOV2020? Please correct in EDC' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:48:48
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 10 (17Nov2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:35
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 03:47:20
User entered '17 Nov 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4)	21 Apr 2021 15:16:39
User entered '18 Nov 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4)	21 Apr 2021 15:07:58
Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 10 (17Nov2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' answered with 'Updated end date in accordance with the symptom log. ' (Site from DM).	Haylee Rowe (b) (4)	21 Apr 2021 14:13:59
DataPoint Un-verified.	Haylee Rowe (b) (4)	21 Apr 2021 14:13:44
Signature has been broken.	Haylee Rowe (b) (4)	21 Apr 2021 14:13:44
User entered '17 Nov 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4)	21 Apr 2021 14:13:44
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 10 (17Nov2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 13:13:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:01:05
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:34:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:34:12

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EAB) (1725)

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:40:20
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:23:17
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:41:06
User entered '92'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Folder: Covid-19 Assessment 12 Nov 2020

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Generated On: 10 Jun 2021 09:41:55

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:41:08
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:41:11
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:41:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:41:15
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
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' for Covid-19 Assessment dated 12NOV2020. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:12:19
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' for Covid-19 Assessment dated 12NOV2020. Please review and update accordingly.' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	23 Feb 2021 16:00:54
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' for Covid-19 Assessment dated 12NOV2020. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 04:33:55
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:41:47
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Folder: Covid-19 Assessment 12 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:42:39
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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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 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:42:41
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:42:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:21
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Un-verified.	(b) (4)	23 Feb 2021 16:00:31
Signature has been broken.	Jamie Pettus (b) (4)	23 Feb 2021 16:00:31
User entered empty; reason for change Data Entry Error	(b) (4)	23 Feb 2021 16:00:31
User signature succeeded.	Jamie Pettus (b) (4)	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	17 Nov 2020 19:42:49
User entered 'No (N)'	(b) (4), (b) (6)	
	Amanda Horn (b) (4)	12 Nov 2020 22:31:15
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:42:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:42:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:24
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Un-verified.	(b) (4)	23 Feb 2021 16:00:31
Signature has been broken.	Jamie Pettus (b) (4)	23 Feb 2021 16:00:31
User entered empty; reason for change Data Entry Error	(b) (4)	23 Feb 2021 16:00:31
User signature succeeded.	Jamie Pettus (b) (4)	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	17 Nov 2020 19:45:47
User entered 'No (N)'	(b) (4), (b) (6)	
	Amanda Horn (b) (4)	12 Nov 2020 22:31:15
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:45:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:45:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:08
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Un-verified.	(b) (4)	23 Feb 2021 16:00:31
Signature has been broken.	Jamie Pettus (b) (4)	23 Feb 2021 16:00:31
User entered empty; reason for change Data Entry Error	(b) (4)	23 Feb 2021 16:00:31
User signature succeeded.	Jamie Pettus (b) (4)	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	17 Nov 2020 19:52:03
User entered 'No (N)'	(b) (4), (b) (6)	
	Amanda Horn (b) (4)	12 Nov 2020 22:31:15
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:07
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Un-verified.	(b) (4)	23 Feb 2021 16:00:31
Signature has been broken.	Jamie Pettus (b) (4)	23 Feb 2021 16:00:31
User entered empty; reason for change Data Entry Error	(b) (4)	23 Feb 2021 16:00:31
User signature succeeded.	Jamie Pettus (b) (4)	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	17 Nov 2020 19:52:09
User entered 'No (N)'	(b) (4), (b) (6)	
	Amanda Horn (b) (4)	12 Nov 2020 22:31:15
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:11
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:01:16
User closed query 'Please reconcile as subject admitted to hospital on 10Nov20 for Hypotension' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:56:03
Query 'Please reconcile as subject admitted to hospital on 10Nov20 for Hypotension' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:34:38
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:34:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:34:12
User opened query 'Please reconcile as subject admitted to hospital on 10Nov20 for Hypotension' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:41:38
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:52:16
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Please reconcile and enter start date and stop date of hypotension meeting criteria in previous question' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:21:33
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:21:30
Query 'Please reconcile and enter start date and stop date of hypotension meeting criteria in previous question' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 16:53:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:52:51
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 16:52:51
User opened query 'Please reconcile and enter start date and stop date of hypotension meeting criteria in previous question' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:56:36
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:52:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:21:37
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:53:49
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 16:53:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:52:20
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:21
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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Folder: Covid-19 Assessment 12 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:28
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:32
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:39
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:41
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:45
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:48
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[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 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:53
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:41:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:56:45
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:56:57
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:57:57
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:57:59
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:37:06
	(b) (4), (b) (6)	
Query 'please verify as yes=+result for D7 in lab portal' canceled (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 14:37:01
	(b) (4), (b) (6)	
User opened query 'please verify as yes=+result for D7 in lab portal' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 22:39:34
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 22:36:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:58:09
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4)	12 Oct 2020 18:50:57
	(b) (4)	

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 14:37:06
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 22:39:04
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:58:12
User entered empty.	Amanda Horn (b) (4)	12 Oct 2020 18:50:57
	(b) (4)	

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:00:51
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:00:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
Query 'please verify as yes=+result for D7 in lab portal' canceled (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 14:37:17
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:37:06
	(b) (4), (b) (6)	
User opened query 'please verify as yes=+result for D7 in lab portal' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 22:39:46
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 22:39:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:01:05
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4)	12 Oct 2020 18:50:57
	(b) (4)	

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:01:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:02:24
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:02:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:02:39
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:02:41
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:03:14
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:03:16
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:03:24
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:03:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:03:38
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:03:39
User entered '16 Nov 2020'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:05:40
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:25:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:25:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:49
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:08:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:05:42
User entered '18 Nov 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 21:25:49
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:05:58
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 18:56:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 18:56:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:53
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:08:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:06:00
User entered '23 Nov 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	23 Nov 2020 18:56:53
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:17:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Nov 2020 22:25:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 22:25:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4)	30 Nov 2020 22:25:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 19:08:13
User entered empty.	System	16 Nov 2020 19:08:13
	Amanda Horn (b) (4)	16 Nov 2020 19:08:13
	(b) (4)	

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:17:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 22:25:19
User entered empty.	Amanda Horn (b) (4)	16 Nov 2020 19:08:13
	(b) (4)	

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:41:55

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:41:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:16:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Dec 2020 16:03:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 16:03:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Dec 2020 16:03:53
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 19:08:13
User entered empty.	System	16 Nov 2020 19:08:13
	Amanda Horn (b) (4)	16 Nov 2020 19:08:13
	(b) (4)	

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:16:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '8 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	08 Dec 2020 16:03:53
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	16 Nov 2020 19:08:13
	(b) (4)	

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:58:06
User closed query 'please verify as 9Oct2020 as per source' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 04:54:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Query 'please verify as 9Oct2020 as per source' answered with 'data updated' (Site from CRA).	(b) (4)	01 Feb 2021 14:42:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Feb 2021 14:41:53
User opened query 'please verify as 9Oct2020 as per source' (Site from CRA).	(b) (4)	28 Jan 2021 14:32:54
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 14:32:31
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:54:27
DataPoint Un-verified.	Amanda Horn (b) (4)	17 Nov 2020 14:31:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 14:31:35
DataPoint Verified.	Amanda Horn (b) (4)	16 Nov 2020 18:49:29
User entered 'Yes (Y)'	(b) (4)	12 Oct 2020 18:49:19

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:58:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Jamie Pettus (b) (4)	01 Feb 2021 14:41:53
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 14:32:34
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:54:31
DataPoint Un-verified.	Amanda Horn (b) (4)	17 Nov 2020 14:31:35
User entered empty; reason for change Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	17 Nov 2020 14:31:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 18:49:31
User entered '9 Oct 2020'	Amanda Horn (b) (4)	12 Oct 2020 18:49:19
	(b) (4)	

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

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 10:23:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:58:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	Jamie Pettus (b) (4)	01 Feb 2021 14:41:53
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 14:32:36
User closed query 'Was this done in the clinic? If so, please correct in EDC.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:54:39
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:54:35
Query 'Was this done in the clinic? If so, please correct in EDC.' answered with 'SUBJECT WAS DIAGNOSED DURING INPATIENT HOSPITALIZATION' (Site from CRA).	Amanda Horn (b) (4)	17 Nov 2020 14:31:42
User entered empty; reason for change Data Entry Error	(b) (4)	
User opened query 'Was this done in the clinic? If so, please correct in EDC.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:50:08
User entered 'Home (Home)'	Amanda Horn (b) (4)	12 Oct 2020 18:49:19
	(b) (4)	

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:08
User entered 'SICKD1'	System	12 Oct 2020 18:49:19

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:50:37
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:50:38
User entered '9 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:50:53
User entered '15:30'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User entered '9 Oct 2020 15:30'	System	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint set to visible.	(b) (4)	01 Feb 2021 14:41:53
DataPoint set to invisible.	System	16 Nov 2020 19:07:38
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:51:01
User entered '065.0' in	Amanda Horn (b) (4)	12 Oct 2020 18:50:16
DataPoint set to visible.	(b) (4)	12 Oct 2020 18:49:19

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint set to visible.	(b) (4)	01 Feb 2021 14:41:53
DataPoint set to invisible.	System	16 Nov 2020 19:07:38
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:51:04
User entered '239.9' lb	Amanda Horn (b) (4)	12 Oct 2020 18:50:16
DataPoint set to visible.	(b) (4)	12 Oct 2020 18:49:19

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:54:56
User closed query 'Delete leading "0".' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:54:55
Query 'Delete leading "0".' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 19:24:21
User entered '98.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:24:15
User opened query 'Delete leading "0".' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:51:37
User entered '098.7' F	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:52:56
User entered 'Other (Other)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:55:02
User entered 'TEMPORAL'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:53:00
User entered '109'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User entered 'bpm'	System	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:55:04
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 19:24:15
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:24:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:53:15
User entered '018'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User entered 'breaths/min'	System	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:53:18
User entered '138'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User entered 'mmHg'	System	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:55:08
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 19:24:15
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:24:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:53:19
User entered '086'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15
User entered 'mmHg'	System	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:15

US3752025

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:53:28
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:23

US3752025

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:53:34
User entered '9 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:23

US3752025

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:41:55

[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 10:23:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:53:46
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:28

US3752025

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:23:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:53:47
User entered '9 Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:39
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:28

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 23:51:47
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 21:01:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:02
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:38

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:04
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:38

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:38

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	16 Nov 2020 19:07:38

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:16
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:20
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	01 Feb 2021 14:41:53

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	01 Feb 2021 14:41:53

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:38
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:44
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:07:44

US3752025

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:03:52
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:49

US3752025

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:04:34
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:49

US3752025

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:41:55

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:04:49
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:54

US3752025

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:04:51
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:07:54

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	11 Dec 2020 22:41:51

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	11 Dec 2020 22:41:51

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:41:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	11 Dec 2020 22:41:51

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:41:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '8 Dec 2020'	(b) (4)	
	Amanda Horn (b) (4)	11 Dec 2020 22:41:51
	(b) (4)	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:41:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Clinic (Clinic)'	(b) (4) Amanda Horn (b) (4) (b) (4)	11 Dec 2020 22:41:51

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	11 Dec 2020 22:41:51

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Yes (Y)'	(b) (4)	11 Dec 2020 22:43:06
	Amanda Horn (b) (4)	
	(b) (4)	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '8 Dec 2020'	(b) (4)	
	Amanda Horn (b) (4)	11 Dec 2020 22:43:06
	(b) (4)	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User closed query 'Per source, time=10:10 while EDC=10:05. Please review and clarify' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 16:15:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:15:20
Query 'Per source, time=10:10 while EDC=10:05. Please review and clarify' answered with 'updated' (Site from CRA).	Jamie Pettus (b) (4)	02 Mar 2021 20:11:36
DataPoint Un-verified.	(b) (4)	
	Jamie Pettus (b) (4)	02 Mar 2021 20:11:21
Signature has been broken.	(b) (4)	
	Jamie Pettus (b) (4)	02 Mar 2021 20:11:21
User entered '10:10' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Jamie Pettus (b) (4)	02 Mar 2021 20:11:21
	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User opened query 'Per source, time=10:10 while EDC=10:05. Please review and clarify' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:42:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '10:05'	Amanda Horn (b) (4)	11 Dec 2020 22:43:06
	(b) (4)	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Dec 2020 10:10'	System	02 Mar 2021 20:11:21
User entered '8 Dec 2020 10:05'	System	11 Dec 2020 22:43:06

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '65.0' in	(b) (4)	11 Dec 2020 22:43:06
DataPoint set to visible.	Amanda Horn (b) (4)	11 Dec 2020 22:41:51
	(b) (4)	
	System	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '249.9' lb	(b) (4) Amanda Horn (b) (4)	11 Dec 2020 22:43:06
DataPoint set to visible.	(b) (4) System	11 Dec 2020 22:41:51

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '98.5' F	(b) (4)	
	Amanda Horn (b) (4)	11 Dec 2020 22:43:06
	(b) (4)	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Oral (Oral)'	(b) (4)	11 Dec 2020 22:43:06
	Amanda Horn (b) (4)	
	(b) (4)	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	11 Dec 2020 22:43:06
	Amanda Horn (b) (4)	
	(b) (4)	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '100'	(b) (4) Amanda Horn (b) (4) (b) (4)	11 Dec 2020 22:43:06

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Dec 2020 22:43:06

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '18'	(b) (4) Amanda Horn (b) (4) (b) (4)	11 Dec 2020 22:43:06

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Dec 2020 22:43:06

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '144'	(b) (4)	11 Dec 2020 22:43:06
	Amanda Horn (b) (4)	
	(b) (4)	

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Dec 2020 22:43:06

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '86'	(b) (4) Amanda Horn (b) (4) (b) (4)	11 Dec 2020 22:43:06

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Dec 2020 22:43:06

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:22
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	11 Dec 2020 22:43:12

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:43:22
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '8 Dec 2020'	(b) (4) Amanda Horn (b) (4) (b) (4)	11 Dec 2020 22:43:12

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:41:55

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	11 Dec 2020 22:43:17

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:41:55

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '8 Dec 2020'	(b) (4)	
	Amanda Horn (b) (4)	11 Dec 2020 22:43:17
	(b) (4)	

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:52:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 19:48:59

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:52:20
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 19:50:18
User entered '22 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 19:48:59

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:52:20
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Feb 2021 19:48:59

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'UNBLND_DECIDE'	System	22 Feb 2021 19:48:59

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:56:45
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:35:35

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:56:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:35:35

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:56:45
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:56:45
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:56:45
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:56:45
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:56:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '1'	System	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:41:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'I'	System	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '165.1' cm	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '110.7' kg	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '40.61192'	System	22 Feb 2021 20:10:05
DataPoint set to visible.	System	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '165.1' cm	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '110.7' kg	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '40.61192'	System	22 Feb 2021 20:10:05
DataPoint set to visible.	System	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '14:35'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '12 Feb 2021 14:35'	System	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '97.5' F	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '95'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'bpm'	System	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '18'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'breaths/min'	System	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '136'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'mmHg'	System	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '96'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'mmHg'	System	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '165.1' cm	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '110.7' kg	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '40.61192'	System	22 Feb 2021 20:10:05
DataPoint set to visible.	System	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '15:54'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '12 Feb 2021 15:54'	System	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '97.9' F	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '95'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'bpm'	System	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '18'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'breaths/min'	System	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '140'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'mmHg'	System	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:02:52
User entered '96'	(b) (4), (b) (6)	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'mmHg'	System	22 Feb 2021 20:10:05

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:10:17

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:03:02
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 20:10:17

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:03:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:10:45

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:03:08
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:10:45

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:03:08
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:10:45

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'mRNA-1273'	System	22 Feb 2021 20:10:45
DataPoint set to visible.	System	22 Feb 2021 19:57:51

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:03:08
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 20:10:45

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:03:08
User entered '15:24'	(b) (4), (b) (6)	22 Feb 2021 20:10:45

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '12 Feb 2021 15:24'	System	22 Feb 2021 20:10:45

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:03:08
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	22 Feb 2021 20:10:45

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:03:08
User entered 'ONCE'	System	22 Feb 2021 20:10:45

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'INTRAMUSCULAR'	System	22 Feb 2021 20:10:45

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:04:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:12:06

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:57
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:24:52
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' answered with 'Accession 1F640739871 tracking (samples 1-5) 914897888304 (samples 6-10) 914897867453' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:44:45
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 10:19:19
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 20:12:06

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:04:27
User entered '15:03'	(b) (4), (b) (6)	22 Feb 2021 20:12:06

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '12 Feb 2021 15:03'	System	22 Feb 2021 20:12:06

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:04:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:12:22

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:04:39
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 20:12:22

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:04:39
User entered '14:39'	(b) (4), (b) (6)	22 Feb 2021 20:12:22

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:55

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '12 Feb 2021 14:39'	System	22 Feb 2021 20:12:22

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:04:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:12:28

US3752025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'I'	System	22 Feb 2021 20:12:28

US3752025

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:21
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:13:54
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 18:36:18

US3752025

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:21
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:13:54
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
User entered '19 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 18:36:18

US3752025

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:21
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:13:54
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 18:36:18

US3752025

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:21
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:13:54
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 18:36:18

US3752025

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:14:01
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 18:36:32

US3752025

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'I'	System	24 Feb 2021 18:36:32

US3752025

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '1'	System	24 Feb 2021 18:36:32
DataPoint set to visible.	System	24 Feb 2021 18:36:32

US3752025

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:51
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:57:40

US3752025

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:51
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '09 Mar 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:57:40

US3752025

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:51
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Clinic (Clinic)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:57:40

US3752025

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'OLD29'	System	09 Mar 2021 19:57:40

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User accepted default value 'Pre-Dose (PREDOSE)'	Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '09 Mar 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '11:20'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 19:59:44
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '09 Mar 2021 11:20'	System	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '98.4' F	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Oral (Oral)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 19:59:44
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '99'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'bpm'	System	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '18'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'breaths/min'	System	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '116'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 19:59:44
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'mmHg'	System	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '78'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'mmHg'	System	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User accepted default value 'Post-Dose (POSTDOSE)'	Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 19:59:44
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '09 Mar 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '12:36'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 19:59:44
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '09 Mar 2021 12:36'	System	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '98.2' F	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Oral (Oral)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 19:59:44
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '97'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'bpm'	System	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '18'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'breaths/min'	System	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '118'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'mmHg'	System	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:08:58
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '80'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'mmHg'	System	09 Mar 2021 19:59:44

US3752025

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 19:59:55
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '09 Mar 2021'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 19:59:55
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:00:09

US3752025

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:00:09
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:00:09
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'mRNA-1273'	System	09 Mar 2021 20:00:09
DataPoint set to visible.	System	24 Feb 2021 18:36:32

US3752025

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '09 Mar 2021'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:00:09
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '12:06'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:00:09
	(b) (4)	

US3752025

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered '09 Mar 2021 12:06'	System	09 Mar 2021 20:00:09

US3752025

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:00:09

US3752025

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:15
User entered 'ONCE'	System	09 Mar 2021 20:00:09

US3752025

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 20:00:09

US3752025

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:07:28
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:00:18

US3752025

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'I'	System	09 Mar 2021 20:00:18

US3752025

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:39
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:12
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Mar 2021 20:51:15

US3752025

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:39
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:12
User entered '16 Mar 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Mar 2021 20:51:15

US3752025

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:39
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Mar 2021 20:51:15

US3752025

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:39
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:12
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	16 Mar 2021 20:51:15
	(b) (4)	

US3752025

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:18:12
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:12
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Mar 2021 20:51:20

US3752025

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:19
User entered 'I'	System	16 Mar 2021 20:51:20

US3752025

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:01
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:36:31

US3752025

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:01
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:36:31

US3752025

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:01
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:36:31

US3752025

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	07 Apr 2021 17:36:31

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:22
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:22
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:22
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '11:05'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '07 Apr 2021 11:05'	System	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:22
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:22
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:22
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered empty.	(b) (4)	07 Apr 2021 17:37:58
	(b) (4), (b) (6)	

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:22
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '89'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:22
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '16'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:22
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '104'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:22
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '74'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 17:37:58

US3752025

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:28
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:38:05

US3752025

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:28
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:38:05

US3752025

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:10:49
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:38:26

US3752025

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:10:49
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:38:26

US3752025

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:10:49
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '11:11'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:38:26

US3752025

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '07 Apr 2021 11:11'	System	07 Apr 2021 17:38:26

US3752025

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:41:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:37:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:22:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:57:57
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 19:36:07

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'Per MM, please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4)	17 Nov 2020 15:57:13
' (Site from DM).	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:22:37
Query 'Per MM, please confirm if this subject was assessed for potential COVID-19 infection.	Amanda Horn (b) (4)	08 Nov 2020 17:04:08
' answered with 'SUBJECT WAS SEEN FOR ILLNESS VISIT 09OCT2020 AND ASSESSED FOR COVID-19' (Site from DM).	(b) (4)	
User opened query 'Per MM, please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	08 Nov 2020 15:54:32
' (Site from DM).		
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 19:00:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Oct 2020 19:00:18
Data point term sent to Coder	System	12 Oct 2020 18:59:04
User entered 'COUGH'	Amanda Horn (b) (4)	12 Oct 2020 18:58:52
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:22:49
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:22:53
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:22:55
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:00
User entered '2 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:02
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User entered empty.	System	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:03
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:06
User entered '11 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:09
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User entered empty.	System	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:14
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:17
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:21
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:23
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:31
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:35
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:37
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:38
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:45
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:48
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:51
User entered 'None (NONE)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:54
User entered 'l'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:56
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:23:59
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:24:03
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User entered '0'	System	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15
User entered 'I'	System	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:15

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'Per MM, please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4)	17 Nov 2020 15:57:17
' (Site from DM).	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:24:55
Query 'Per MM, please confirm if this subject was assessed for potential COVID-19 infection.	Amanda Horn (b) (4)	08 Nov 2020 17:04:52
' answered with 'SUBJECT WAS SEEN 08OCT2020 FOR ILLNESS VISIT. COVID PCR WAS NEGATIVE' (Site from DM).	(b) (4)	
User opened query 'Per MM, please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	08 Nov 2020 15:54:48
' (Site from DM).		
User closed query 'Per DM CLR: Please review AE and please update to indicate whether the recorded Chest Tightness is Cardiac or Non-cardiac related. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 15:54:44
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:48:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:48:26
Data point term sent to Coder	System	02 Nov 2020 15:12:13
Query 'Per DM CLR: Please review AE and please update to indicate whether the recorded Chest Tightness is Cardiac or Non-cardiac related. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.'	Amanda Horn (b) (4)	02 Nov 2020 15:11:44
answered with 'UPDATED' (Site from DM).	(b) (4)	
Coding entries removed.	Amanda Horn (b) (4)	02 Nov 2020 15:11:37
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'NON-CARDIAC CHEST TIGHTNESS' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Nov 2020 15:11:37
User opened query 'Per DM CLR: Please review AE and please update to indicate whether the recorded Chest Tightness is Cardiac or Non-cardiac related. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\\23.0.	(b) (4), (b) (6)	02 Nov 2020 14:28:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 19:01:23
Data point term sent to Coder	(b) (4)	
User entered 'CHEST TIGHTNESS'	Coder Import (b) (4)	12 Oct 2020 19:01:23
	System	12 Oct 2020 19:00:08
	Amanda Horn (b) (4)	12 Oct 2020 18:59:25
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:11
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:15
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:17
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:23
User entered '2 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User entered empty.	System	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:26
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:28
User entered '9 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:31
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User entered empty.	System	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:35
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:39
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:41
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:42
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:44
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:47
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:48
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:51
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:54
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:25:56
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:00
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:01
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:04
User entered 'None (NONE)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:07
User entered 'l'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:09
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:10
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:16
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User entered '0'	System	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21
User entered '1'	System	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:17:21

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:49:29
User entered 'USA-US113-2020-mRNA-1273-P301000013'	System	13 Nov 2020 15:49:25
User entered 'New'	(b) (4), (b) (6)	13 Nov 2020 15:49:25

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'Safety Medical Query: Please consider updating event term 'HYPOTENSION REQUIRING HOSPITALIZATION' to HYPOTENSION as 'hospitalization' is seriousness criterion and should no be included in the event term. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:11:57
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:21:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:21:54
Query 'Safety Medical Query: Please consider updating event term 'HYPOTENSION REQUIRING HOSPITALIZATION' to HYPOTENSION as 'hospitalization' is seriousness criterion and should no be included in the event term. ' answered with 'UPDATED' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:21:21
Data point term sent to Coder	System	14 Dec 2020 17:20:36
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:20:02
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:20:02
User entered 'HYPOTENSION' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:20:02
User opened query 'Safety Medical Query: Please consider updating event term 'HYPOTENSION REQUIRING HOSPITALIZATION' to HYPOTENSION as 'hospitalization' is seriousness criterion and should no be included in the event term. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:44:59
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:26:28

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:02:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:02:35
Data point term sent to Coder	System	12 Nov 2020 21:07:25
User entered 'Hypotension requiring hospitalization'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:29
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:34
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:37
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:40
User entered '10 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:26:42
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	12 Nov 2020 21:08:06
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4)	12 Nov 2020 21:08:06
	(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	12 Nov 2020 21:06:51
User entered '00:00'	Haylee Rowe (b) (4)	12 Nov 2020 21:06:51
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:08:06
User entered '10 Nov 2020 00:00'	System	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:43
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	13 Nov 2020 21:01:13
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:45
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	13 Nov 2020 21:01:13
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	13 Nov 2020 21:01:13
User entered '13 Nov 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	13 Nov 2020 21:01:13
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	13 Nov 2020 21:00:35
User entered empty.	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:48
User entered empty.	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved). ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:04:25
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:46:31
User entered empty.	System	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:52
User entered 'Grade 4 (Grade 4)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:54
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:58
User entered '0'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:00
User entered '0'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:57:27
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:27:16
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'SUBJECT REMAINS HOSPITALIZED AT THIS TIME' (Site from System).	Amanda Horn (b) (4) (b) (4)	13 Nov 2020 15:21:26
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Nov 2020 21:06:51
User entered 'I'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:17
User entered '10 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:19
User entered '13 Nov 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	13 Nov 2020 20:55:04
User entered empty.	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:20
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:24
User entered empty.	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:25
User entered '0'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:27
User entered '0'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:28
User entered '0'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:30
User entered 'Not Related (NOT RELATED)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:36
User entered 'Not Related (NOT RELATED)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:37
User entered 'Not Applicable (NOT APPLICABLE)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

None

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:27:41
User entered '0'	Haylee Rowe (b) (4)	12 Nov 2020 21:06:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:42
User entered 'I'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:44
User entered '0'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:12:13
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'UPDATED' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:20:14
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:46:09
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:27:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	13 Nov 2020 21:00:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:27:49
User entered empty.	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:12:27
User closed query 'PV Query: Please provide the subject's BP at discharge/event resolution. ' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 17:12:24
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'UPDATED' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:20:24
Query 'PV Query: Please provide the subject's BP at discharge/event resolution. ' answered with 'UPDATED' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:20:20
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:20:02
User entered 'PATIENT CONTACTED STUDY SITE TODAY, 12 NOV 2020, AND REPORTED THAT SHE HAS BEEN IN THE HOSPITAL SINCE 10 NOV 2020.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:20:02
SUBJECT'S BLOOD PRESSURE WAS MEASURED AT 89/66 IN THE EMERGENCY ROOM. UPON DISCHARGE ON 13NOV2020 BP WAS 114/79' reason for change: Data Entry Error		
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:45:41
User opened query 'PV Query: Please provide the subject's BP at discharge/event resolution. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:45:27
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 17:48:34
User closed query 'PV Query: Please provide BP measurements from baseline and relevant BP measurements documenting the event hypotension requiring hospitalization. ' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 15:13:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide BP measurements from baseline and relevant BP measurements documenting the event hypotension requiring hospitalization. ' answered with 'updated' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:31
	(b) (4), (b) (6)	19 Nov 2020 17:24:21
User entered 'PATIENT CONTACTED STUDY SITE TODAY, 12 NOV 2020, AND REPORTED THAT SHE HAS BEEN IN THE HOSPITAL SINCE 10 NOV 2020.	(b) (4), (b) (6)	19 Nov 2020 17:24:21
Subject's blood pressure was measured at 89/66 in the emergency room.' reason for change: Data Entry Error		
User opened query 'PV Query: Please provide BP measurements from baseline and relevant BP measurements documenting the event hypotension requiring hospitalization. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:31:32
	(b) (4), (b) (6)	16 Nov 2020 17:27:57
User entered 'Patient contacted study site today, 12 Nov 2020, and reported that she has been in the hospital since 10 Nov 2020.'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 21:06:51

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 21:06:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4)	17 Nov 2020 20:07:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:28:16
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:28:13
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:38
User entered 'USA-US113-2020-mRNA-1273-P301000013'	(b) (4), (b) (6)	13 Nov 2020 15:50:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:01:40
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 14:53:53
	(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 14:53:53
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 14:53:31
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.	System	23 Nov 2020 14:53:04
' (Site from System).		
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.	(b) (4), (b) (6)	23 Nov 2020 14:53:04
' answered with 'updated' (Site from System).		
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:52:54
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 14:52:54
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 14:52:54
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.	Coder Import (b) (4)	23 Nov 2020 12:24:21
	(b) (4)	
' (Site from System).		
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:07:53
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)	12 Nov 2020 22:08:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	12 Nov 2020 22:08:35 12 Nov 2020 22:08:11
User entered 'SYMPTOMATIC COVID-19'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:07:56
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:04
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 14:40:22
User closed query 'Source says start date is 08NOV2020. Please update in EDC' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:40:20
Query 'Source says start date is 08NOV2020. Please update in EDC' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:05:24
User entered '08 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:05:15
User opened query 'Source says start date is 08NOV2020. Please update in EDC' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:09:23
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 20:08:39
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:08:18
User entered '10 Nov 2020'	Amanda Horn (b) (4)	12 Nov 2020 22:07:17
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:09:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'Per MM, Please provide end date and final outcome. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 23:16:05
Query 'Per MM, Please provide end date and final outcome. ' answered with 'UPDATED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:22:43
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:22:19
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:22:19
User opened query 'Per MM, Please provide end date and final outcome. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 23:24:59
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:09:30
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Un-verified.	(b) (4)	14 Dec 2020 17:22:19
User entered '30 Nov 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	14 Dec 2020 17:22:19
DataPoint Verified.	(b) (4)	17 Nov 2020 20:09:37
User entered empty.	Amanda Horn (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:09:39
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:40:29
	(b) (4), (b) (6)	
User closed query 'Source says Grade 4. Update edc or clarify.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:40:25
	(b) (4), (b) (6)	
Query 'Source says Grade 4. Update edc or clarify.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:05:30
	(b) (4), (b) (6)	
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:05:15
	(b) (4), (b) (6)	
User opened query 'Source says Grade 4. Update edc or clarify.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:10:08
	(b) (4), (b) (6)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Amanda Horn (b) (4)	12 Nov 2020 22:07:17
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:39
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:43
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:48
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 15:57:35
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'PARTICIPANT HAS NOT YET BEEN DISCHARGED' (Site from System).	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:53
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:07:17
User entered 'I'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:15:02
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:11:20
User entered 'No (N)'	Amanda Horn (b) (4)	12 Nov 2020 22:07:17
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:22
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:29
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:31
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:35
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:39
User entered 'Not Applicable (NOT APPLICABLE)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

None

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:41
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:11:45
User entered 'I'	Amanda Horn (b) (4)	12 Nov 2020 22:07:17
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:17:02
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'data changed' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	18 Jan 2021 15:37:10
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 06:13:26
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:22:19
User entered '1' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:22:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:11:49
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Un-verified.	(b) (4)	14 Dec 2020 17:22:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Amanda Horn (b) (4)	14 Dec 2020 17:22:19
Data Entry Error	(b) (4)	14 Dec 2020 17:22:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:11:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amanda Horn (b) (4)	12 Nov 2020 22:07:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:11:59
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Nov 2020 15:28:37
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	13 Nov 2020 15:28:37
User entered 'THE SUBJECT WAS ADMITTED TO INPATIENT FACILITY 10NOV2020 AND HAS NOT YET BEEN DISCHARGED.' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	13 Nov 2020 15:28:37
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Nov 2020 22:07:17
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:31:15
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Per PI discretion, no this subject was not assessed for potential covid infection due to having multiple health issues along with already having covid before the new year. ' (Site from DM).	Haylee Rowe (b) (4)	30 Mar 2021 15:16:05
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	06 Mar 2021 16:13:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 16:13:02
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) (6)	02 Mar 2021 16:50:57
Data point term sent to Coder	System	01 Mar 2021 19:20:31
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 'updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:20:27
Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:20:17
User entered 'worsening INTRACTABLE HEADACHE' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:20:17

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
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)	23 Feb 2021 08:42:28
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:47:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:47:29
Data point term sent to Coder	System	04 Feb 2021 20:06:57
User entered 'INTRACTABLE HEADACHE' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 20:06:49
Data point term sent to Coder	System	04 Feb 2021 18:39:48
User entered 'INTRACTABLE HEADACHE, UNSPECIFIED CHRONICITY PATTERN, UNSPECIFIED HEADACHE TYPE'	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:39:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:39:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '11 Jan 2021'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 18:39:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:39:40

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User closed query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:02:53
Query 'Per MM, please provide the end date.' answered with 'This is till ongoing for patient. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	30 Mar 2021 15:15:22
User opened query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 20:22:05
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or has returned to baseline state and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 16:29:48
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or has returned to baseline state and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'AE IS STILL ONGOING' (Site from DM).	Amanda Horn (b) (4) (b) (4)	17 Mar 2021 20:52:03
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or has returned to baseline state and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:53:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:39:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:39:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 18:39:40
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:39:40

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:39:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:39:40

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:39:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:39:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 18:39:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 18:39:47
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amanda Horn (b) (4)	04 Feb 2021 18:39:47
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 18:39:40
User entered empty.	System	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	04 Feb 2021 18:39:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'I'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 18:39:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:39:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:39:40
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 18:39:40

US3752025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	04 Feb 2021 18:39:40

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Folder: Adverse Events

Form: Adverse Events (6)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:30:14
User entered 'USA-US113-2021-mRNA-1273-P301000005'	System	05 Feb 2021 15:36:09
User entered 'New'	(b) (4), (b) (6)	05 Feb 2021 15:36:09

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition Left Renal Mass. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 22:23:09
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition Left Renal Mass. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'There was not a worsening of the MH condition but further diagnostic procedures provided diagnosis.' (Site from DM).	Amanda Horn (b) (4) (b) (4)	17 Mar 2021 20:48:50
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition Left Renal Mass. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:53:46
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:12:20
User closed query 'PV Query: Was the SAE considered a worsening of the subject's medical history of left renal mass?' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 17:05:26
Query 'PV Query: Was the SAE considered a worsening of the subject's medical history of left renal mass?' answered with 'yes' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:19:15
User opened query 'PV Query: Was the SAE considered a worsening of the subject's medical history of left renal mass?' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 18:55:53
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Clear cell renal cell carcinoma, LLT: Clear cell renal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 21:09:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 21:09:27
Data point term sent to Coder	System	04 Feb 2021 18:57:29
User entered 'CLEAR CELL RENAL CARCINOMA'	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4)	04 Feb 2021 18:56:49
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	04 Feb 2021 18:56:49
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:41:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

US3752025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '22 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

US3752025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:56:49
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:56:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	11 Mar 2021 16:24:42
User entered 'No (N)' reason for change: Data Entry Error	System	11 Mar 2021 16:24:42
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Lauren Evans (b) (4)	11 Mar 2021 16:24:23
User entered 'Yes (Y)'	System	11 Mar 2021 16:24:23
	Amanda Horn (b) (4)	04 Feb 2021 18:56:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:36
Signature has been broken.	(b) (4) Haylee Rowe (b) (4)	18 Mar 2021 16:10:29
User entered '23 Jan 2021' reason for change: Data Entry Error	(b) (4) Haylee Rowe (b) (4)	18 Mar 2021 16:10:29
User signature succeeded.	(b) (4) Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:30:01
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'data has been updated because event is resolved' (Site from Safety).	Lauren Evans (b) (4)	11 Mar 2021 16:24:58
User entered '22 Jan 2021' reason for change: Data Entry Error	Lauren Evans (b) (4)	11 Mar 2021 16:24:23
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 18:55:08
User entered empty.	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

US3752025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:56:49
	Amanda Horn (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:56:49

US3752025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

US3752025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4)	04 Feb 2021 18:56:49
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

US3752025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

US3752025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'I'	(b) (4)	04 Feb 2021 18:56:49
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '22 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '23 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

US3752025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	04 Feb 2021 18:56:49
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:56:49
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

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Folder: Adverse Events

Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 18:56:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:41:55

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4)	04 Feb 2021 18:56:49
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	22 Mar 2021 14:33:32
	Priyantha Wijewardane	20 Mar 2021 01:28:36
	(b) (4)	
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'UPDATED' (Site from DM). Signature has been broken.	Amanda Horn (b) (4)	17 Mar 2021 20:50:38
	(b) (4)	
	Amanda Horn (b) (4)	17 Mar 2021 20:50:30
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Mar 2021 20:50:30
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	17 Mar 2021 18:54:04
	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 17:05:57

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'done' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:25:47
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	10 Feb 2021 18:55:31
User entered 'I'	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Jamie Pettus (b) (4)	01 Mar 2021 19:16:30
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 19:01:53
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 18:59:59
User entered '0'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 18:56:49
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:30:07
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'data updated per query' (Site from Safety).	Lauren Evans (b) (4)	11 Mar 2021 16:26:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lauren Evans (b) (4)	11 Mar 2021 16:24:23
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 18:54:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 18:56:49

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	04 Feb 2021 18:56:49
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:16:10
User closed query 'Per DM CLR: Narrative = LEFT RENAL MASS WITH START DATE 31JUL2020. However, this is not the recorded start date in the MH eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 22:23:19
Query 'Per DM CLR: Narrative = LEFT RENAL MASS WITH START DATE 31JUL2020. However, this is not the recorded start date in the MH eCRF. Please review and reconcile data as appropriate.' answered with 'THE CORRECT DATE IS 20 JUL 2020' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:43:31
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:43:19
User entered 'MEDICAL HISTORY INCLUDES LEFT RENAL MASS WITH START DATE 20JUL2020. SCHEDULED INPATIENT PROCEDURE WITH PATHOLOGY INDICATING CLEAR CELL RENAL CARCINOMA. FOLLOW UP WITH UROLOGY SCHEDULED FOR 09FEB2021. NO COVID TESTING DONE DURING THIS ADMISSION.' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 15:43:19
User opened query 'Per DM CLR: Narrative = LEFT RENAL MASS WITH START DATE 31JUL2020. However, this is not the recorded start date in the MH eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 03:19:03
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 14:39:43
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'End date is 23 OCT 2021' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	18 Mar 2021 16:11:13

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) [REDACTED]	18 Mar 2021 15:07:15
	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6) [REDACTED]	02 Mar 2021 17:06:07
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	02 Mar 2021 17:06:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'PATHOLOGY REPORT FAXED. NO OTHER RELEVANT LABORATORY OR DIAGNOSTIC TEST RESULTS AVAILABLE.' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:35:16
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'UPDATED' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	01 Mar 2021 19:31:13

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'MEDICAL HISTORY INCLUDES LEFT RENAL MASS WITH START DATE 31JUL2020. SCHEDULED INPATIENT PROCEDURE WITH PATHOLOGY INDICATING CLEAR CELL RENAL CARCINOMA. FOLLOW UP WITH UROLOGY SCHEDULED FOR 09FEB2021. NO COVID TESTING DONE DURING THIS ADMISSION.' reason for change: Data Entry Error	Amanda Horn (b) (4)	01 Mar 2021 19:30:00
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 18:54:31
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 18:54:09
User entered 'MEDICAL HISTORY INCLUDES LEFT RENAL MASS WITH START DATE 31JUL2020. SCHEDULED INPATIENT PROCEDURE WITH PATHOLOGY INDICATING CLEAR CELL RENAL CARCINOMA. FOLLOW UP WITH UROLOGY SCHEDULED FOR 09FEB2021' reason for change: Data Entry Error	Amanda Horn (b) (4)	04 Feb 2021 18:59:59
User entered 'FOLLOW UP WITH UROLOGY SCHEDULED FOR 09FEB2021'	Amanda Horn (b) (4)	04 Feb 2021 18:56:49

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	04 Feb 2021 18:56:49

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Folder: Adverse Events

Form: Adverse Events (6)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Feb 2021 18:56:49

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Folder: Adverse Events

Form: Adverse Events (6)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 18:56:49

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Folder: Adverse Events

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:42:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:42:41
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User closed query 'Per DM CLR: Please specify type of PROCEDURE done and include in AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:32:01
Data point term sent to Coder	System	01 Mar 2021 19:24:39
User entered 'POST-PROCEDURE PAIN PARTIAL (NEPHRECTOMY)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:24:20
Query 'Per DM CLR: Please specify type of PROCEDURE done and include in AE eCRF.' answered with 'done' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:23:52
Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:23:43
User entered 'POST-PROCEDURE PAIN partial nephrectomy' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:23:43
User opened query 'Per DM CLR: Please specify type of PROCEDURE done and include in AE eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 08:43:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:04:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:04:50
Data point term sent to Coder	System	04 Feb 2021 20:03:55

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'POST-PROCEDURE PAIN'	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 20:03:07

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '22 Jan 2021'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
User entered empty.	System	04 Feb 2021 20:03:07

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered '2 Feb 2021'	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
User entered empty.	System	04 Feb 2021 20:03:07

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered 'l'	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Amanda Horn (b) (4) (b) (4)	04 Feb 2021 20:03:07

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

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 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	04 Feb 2021 20:03:07
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
User entered '0'	System	04 Feb 2021 20:03:07

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19
User entered '1'	System	04 Feb 2021 20:03:07

US3752025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:19

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Mar 2021 20:00:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 20:00:43
Data point term sent to Coder	System	09 Mar 2021 19:59:47
User entered 'hypertension'	Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4)	09 Mar 2021 19:59:05
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	
	Jamie Pettus (b) (4)	09 Mar 2021 19:59:05
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	
	Jamie Pettus (b) (4)	09 Mar 2021 19:59:05
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '19 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	09 Mar 2021 19:59:05
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 19:59:05
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 19:59:05
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 19:59:05
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Jamie Pettus (b) (4)	09 Mar 2021 19:59:05
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	
	Jamie Pettus (b) (4)	09 Mar 2021 19:59:05
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 19:59:05
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 19:59:05
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 19:59:05
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 19:59:05
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Jamie Pettus (b) (4)	09 Mar 2021 19:59:05
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'I'	(b) (4)	
	Jamie Pettus (b) (4)	09 Mar 2021 19:59:05
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	09 Mar 2021 19:59:05
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'saw PCP and got ramapril'	(b) (4) Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:41:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Mar 2021 19:59:05

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
User closed query 'Per MM: Please update to the underlying diagnosis, if known.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 19:59:25
Query 'Per MM: Please update to the underlying diagnosis, if known.' answered with 'The lower lung rhonchi was auscultated on the Physical Exam. There is no underlying diagnosis. Pt. was seen by regular PCP and the lower lung rhonci was clear. Pt. has COPD and is an everyday nicotine user. ' (Site from DM).	Haylee Rowe (b) (4)	26 Apr 2021 13:08:12
User opened query 'Per MM: Please update to the underlying diagnosis, if known.' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 14:53:44
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Lower respiratory tract signs and symptoms, PT: Rhonchi, LLT: Rhonchi - 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 Mar 2021 21:12:57
Data point term sent to Coder	(b) (4)	
User entered 'BILATERAL LOWER LUNG RHONCHI'	System	10 Mar 2021 18:21:30
	Haylee Rowe (b) (4)	10 Mar 2021 18:21:10
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '09 Mar 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Mar 2021 18:21:25
User entered '00:00' reason for change: Data Entry Error	Haylee Rowe (b) (4)	10 Mar 2021 18:21:25
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Mar 2021 18:21:10
User entered empty.	Haylee Rowe (b) (4)	10 Mar 2021 18:21:10
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
User entered '09 Mar 2021 00:00'	System	10 Mar 2021 18:21:25
User entered empty.	System	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:39:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:39:11
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:39:11
User entered '07 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:39:11
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Apr 2021 17:39:21
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:39:21
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:39:21
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Apr 2021 17:39:11
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	Haylee Rowe (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
User entered '07 Apr 2021 00:00'	System	07 Apr 2021 17:39:21
User entered empty.	System	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4)	
	Haylee Rowe (b) (4)	10 Mar 2021 18:21:10
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	10 Mar 2021 18:21:10
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	10 Mar 2021 18:21:10
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	10 Mar 2021 18:21:10
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	10 Mar 2021 18:21:10
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'None (NONE)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'l'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:39:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:39:11
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Unknown (UNKNOWN)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	10 Mar 2021 18:21:10
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	10 Mar 2021 18:21:10
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
User entered '0'	System	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12
User entered '0'	System	10 Mar 2021 18:21:10

US3752025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:11:12

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in knee - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	08 Apr 2021 06:48:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:48:41
Data point term sent to Coder	System	07 Apr 2021 18:54:53
User entered 'increased pain in right knee'	Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '31 Mar 2021'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered empty.	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
DataPoint Un-verified.	Haylee Rowe (b) (4)	23 Apr 2021 18:39:20
	(b) (4)	
Signature has been broken.	Haylee Rowe (b) (4)	23 Apr 2021 18:39:20
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	23 Apr 2021 18:39:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
	(b) (4)	
User entered 'Yes (Y)'	Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
DataPoint Un-verified.	Haylee Rowe (b) (4)	23 Apr 2021 18:39:20
	(b) (4)	
Signature has been broken.	Haylee Rowe (b) (4)	23 Apr 2021 18:39:20
	(b) (4)	
User entered '23 Apr 2021' reason for change: Data Entry Error	Haylee Rowe (b) (4)	23 Apr 2021 18:39:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered empty.	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '0'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '0'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '0'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered empty.	(b) (4)	07 Apr 2021 18:54:05
	Lauren Evans (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered empty.	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered empty.	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered empty.	(b) (4)	07 Apr 2021 18:54:05
	Lauren Evans (b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '0'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '0'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '0'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Not Related (NOT RELATED)'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Not Related (NOT RELATED)'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'None (NONE)'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '0'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 03:44:25
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Un-verified.	(b) (4)	20 Apr 2021 19:37:24
Signature has been broken.	Haylee Rowe (b) (4)	20 Apr 2021 19:37:24
User entered '1' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 19:37:24
DataPoint Verified.	Haylee Rowe (b) (4)	20 Apr 2021 15:50:50
User signature succeeded.	(b) (4), (b) (6)	08 Apr 2021 13:38:56
User entered '0'	Priyantha Wijewardane	07 Apr 2021 18:54:05
	(b) (4)	
	Lauren Evans (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'I'	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
DataPoint Un-verified.	Haylee Rowe (b) (4)	23 Apr 2021 18:39:20
	(b) (4)	
Signature has been broken.	Haylee Rowe (b) (4)	23 Apr 2021 18:39:20
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Haylee Rowe (b) (4)	23 Apr 2021 18:39:20
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lauren Evans (b) (4)	07 Apr 2021 18:54:05

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered empty.	(b) (4) Lauren Evans (b) (4)	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:50
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered empty.	(b) (4)	07 Apr 2021 18:54:05
	Lauren Evans (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 18:54:05

US3752025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:41:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 18:54:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:41:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:37:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:28:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 19:36:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 20:27:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 20:18:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:29:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:36:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:36:08
Data point term sent to Coder	System	12 Aug 2020 19:35:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
Data point term sent to Coder	System	11 Aug 2020 20:28:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:23:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:23:20
Data point term sent to Coder	System	11 Aug 2020 20:22:07
Data point term sent to Coder	System	11 Aug 2020 20:21:07
User entered 'Levemir'	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:29:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 20:21:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:29:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 20:21:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 20:21:26
User entered 'Diabetes mellitus type II' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 20:21:26
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 20:21:03
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 20:21:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Per CDM: Please remove Dose Unit in Dose per Administration field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:29:07
Query 'Per CDM: Please remove Dose Unit in Dose per Administration field.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:14:52
User entered '26' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 14:14:43
User opened query 'Per CDM: Please remove Dose Unit in Dose per Administration field.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:58:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered '26 units'	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Per CDM : Please not that Dose Unit "IU" which means International Unit is an available option. Kindly determine if it would be a more appropriate answer. Please review and reconcile as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:56:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:29:13
Query 'Per CDM : Please not that Dose Unit "IU" which means International Unit is an available option. Kindly determine if it would be a more appropriate answer. Please review and reconcile as appropriate. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:15:02
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 14:14:43
User opened query 'Per CDM : Please not that Dose Unit "IU" which means International Unit is an available option. Kindly determine if it would be a more appropriate answer. Please review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:01:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 20:21:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 20:21:53
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 20:21:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 20:21:03
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 20:21:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:29:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 14:14:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered 'units' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 20:21:53
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:29:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:29:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:29:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:29:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:29:31
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 15:09:22
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	12 Aug 2020 19:35:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
User closed 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	11 Aug 2020 20:27:54
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.' answered by data change (Site from System).	System	11 Aug 2020 20:27:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
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	11 Aug 2020 20:21:03
User entered 'un UNK 2020'	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:29:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Source states this med continues. Please update EDC or clarify.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:18:46
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:18:44
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 14:58:36
Query 'Source states this med continues. Please update EDC or clarify.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:10:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:10:48
User opened query 'Source states this med continues. Please update EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:30:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:29:58
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:29:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 14:56:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:22:14
User entered '2 Sep 2020' reason for change: New Information	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 14:58:36
User entered empty; reason for change New Information	(b) (4), (b) (6)	16 Nov 2020 18:10:48
User entered '04 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	30 Oct 2020 14:56:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:30:56
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:59:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 16:59:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 16:59:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 20:21:03
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered '2'	System	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered '1'	System	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Aug 2020 19:35:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Aug 2020 20:27:54
User entered '804 (804)'	System	11 Aug 2020 20:21:03

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:05:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:05:41
Data point term sent to Coder	System	19 Oct 2020 16:04:44
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 16:03:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:07:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:07:25
Data point term sent to Coder	System	12 Aug 2020 20:06:27
User entered 'metformin'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:10
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:31:11
User entered 'Diabetes mellitus type 2' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:03:44
User entered 'DM II'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:13
User entered '1000'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:15
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:16
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:31:18
User entered 'twice daily (BID)'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:21
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:26
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:31:31
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 15:09:31
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	12 Aug 2020 20:05:41
User entered 'UN UNK 2020'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:35
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:40
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:42
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:05:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:23:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:06:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:06:52
Data point term sent to Coder DataPoint Un-verified.	System Amanda Horn (b) (4)	16 Nov 2020 20:05:35 16 Nov 2020 20:05:08
Coding entries removed.	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Nov 2020 20:05:08
User entered 'ATORVASTATIN' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 20:05:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:34:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:08:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:08:11
Data point term sent to Coder User entered 'SIMVASTATIN'	System (b) (4), (b) (6)	12 Aug 2020 20:07:28 12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:32
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:34
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:36
User entered '40'	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:38
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:40
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	16 Nov 2020 17:34:42
	(b) (4), (b) (6)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:44
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:45
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:47
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:50
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 15:09:37
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	12 Aug 2020 20:06:45
User entered 'UN UNK 2020'	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:52
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:34:57
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:12
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:06:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	22 Apr 2021 15:18:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:00:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 16:21:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 16:21:03
Data point term sent to Coder	System	21 Apr 2021 16:20:23
DataPoint Un-verified.	Haylee Rowe (b) (4)	21 Apr 2021 16:20:09
Coding entries removed.	(b) (4) Haylee Rowe (b) (4)	21 Apr 2021 16:20:09
Signature has been broken.	(b) (4) Haylee Rowe (b) (4)	21 Apr 2021 16:20:09
User entered 'Sertraline' reason for change: Data Entry Error	(b) (4) Haylee Rowe (b) (4)	21 Apr 2021 16:20:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:08:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:08:11
Data point term sent to Coder	System	12 Aug 2020 20:07:30
User entered 'ZOLOFT'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:26
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:30
User entered 'ANXIETY'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:33
User entered '75'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:35
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:37
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:43
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:50
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:51
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 15:09:42
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	12 Aug 2020 20:07:24
User entered 'UN UNK 2019'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:35:54
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:53:13
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:12
DataPoint Un-verified.	(b) (4)	
	Amanda Horn (b) (4)	16 Mar 2021 20:52:38
Signature has been broken.	(b) (4)	
	Amanda Horn (b) (4)	16 Mar 2021 20:52:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	16 Mar 2021 20:52:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:35:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:53:15
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:12
DataPoint Un-verified.	(b) (4)	
	Amanda Horn (b) (4)	16 Mar 2021 20:52:38
Signature has been broken.	(b) (4)	
	Amanda Horn (b) (4)	16 Mar 2021 20:52:38
User entered '2 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	16 Mar 2021 20:52:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:36:00
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:36:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User entered '1'	System	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User entered '1'	System	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:07
User entered '804 (804)'	System	12 Aug 2020 20:07:24

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:36:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:06:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:06:44
Data point term sent to Coder	System	19 Oct 2020 16:05:46
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 16:04:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:35:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:35:15
Data point term sent to Coder	System	26 Aug 2020 14:41:53
User closed query 'For coding purposes, references indicate different formulations for PROTONIX. Please provide generic ingredients, complete, accurate trade name and update the term with your response.' (Site from System).	System	26 Aug 2020 14:41:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
Query 'For coding purposes, references indicate different formulations for PROTONIX. Please provide generic ingredients, complete, accurate trade name and update the term with your response.' answered with 'Generic for Protonix is pantoprazole' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 14:41:13
Data point term sent to Coder	System	26 Aug 2020 14:40:52
User entered 'PROTONIX (pantoprazole)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:40:44
User opened query 'For coding purposes, references indicate different formulations for PROTONIX. Please provide generic ingredients, complete, accurate trade name and update the term with your response.' (Site from System).	Coder Import (b) (4)	14 Aug 2020 19:35:26
Data point term sent to Coder	System	12 Aug 2020 20:08:31
User entered 'PROTONIX'	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:36:49
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	17 Nov 2020 20:24:21
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:38:27
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:37:01
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	19 Oct 2020 16:04:52
reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 20:08:14
User entered 'ABDOMINAL ISSUES'	(b) (4), (b) (6)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:38:35
User entered '40'	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:38:37
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:38:39
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	16 Nov 2020 17:38:48
	(b) (4), (b) (6)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:38:51
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:38:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:39:03
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 15:09:47
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	12 Aug 2020 20:08:14
User entered 'UN UNK 2017'	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:39:11
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:39:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:39:35
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	16 Nov 2020 17:39:41
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:08:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:39:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:22:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:22:51
Data point term sent to Coder	System	21 Sep 2020 20:27:46
User entered 'Influenza vaccination'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:39:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:39:57
User entered 'Prophylaxis for seasonal influenza'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:00
User entered 'l'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:02
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:03
User entered 'injection'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:06
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:08
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:11
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:12
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:20
User entered '03 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:22
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:23
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:25
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	21 Sep 2020 20:27:16
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 20:27:16
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	21 Sep 2020 20:26:59
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:40:28
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User entered empty.	System	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User entered empty.	System	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:11
User entered empty.	System	21 Sep 2020 20:26:59

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:40:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 08:22:20
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 08:22:20
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 16:06:51
User entered 'Humalog Kwik Pen'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:40:38
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:40:41
User entered 'Diabetes mellitus type 2'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:40:44
User entered '12'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:53:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 14:33:54
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 14:33:54
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:40:46
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:53:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query ' Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:31:19
Query ' Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:34:03
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 14:33:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 14:33:54
User opened query ' Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:25:51
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:40:48
User entered 'units'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:40:50
User entered 'twice daily (BID)'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:40:53
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:40:56
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:41:10
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:41:06
User entered '15 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:41:08
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:25:32
DataPoint Un-verified.	Amanda Horn (b) (4)	17 Nov 2020 14:59:58
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 14:59:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:41:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:25:37
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	17 Nov 2020 15:00:05
User entered 'UN Nov 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 15:00:05
	(b) (4)	
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	17 Nov 2020 14:59:58
DataPoint Un-verified.	Amanda Horn (b) (4)	17 Nov 2020 14:59:58
	(b) (4)	
User entered 'UN Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 14:59:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:41:15
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:41:16
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User entered '2'	System	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User entered '1'	System	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:38
User entered '804 (804)'	System	19 Oct 2020 16:06:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:09:39
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES should be recorded, and update con med indication or provide clarification. ' answered with 'routine addition with no noted worsening of condition' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 14:39:14
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:56:42
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:26:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:02:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:02:53
Data point term sent to Coder	System	30 Oct 2020 14:57:59
User entered 'Humalog'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:08
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:20
User entered 'Diabetes II'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:23
User entered 'VARIES' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:01:52
User entered '12' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 20:22:21
User entered 'continuous'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:25
User entered 'Other (OTHER)' reason for change:	Amanda Horn (b) (4)	17 Nov 2020 15:01:52
Data Entry Error	(b) (4)	
User entered 'IU (IU)'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:28
User entered 'UNITS' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:01:52
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:32
User entered 'other (OTHER)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:01:52
User entered 'twice daily (BID)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 20:22:21
User entered 'other (OTHER)'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:39
User entered 'CONTINUOUS PUMP WITH MEALTIME BOLUS' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:01:52
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 20:22:21
User entered 'continuous'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:41
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:44
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:47
User entered 'UN Nov 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:01:52
User entered '04 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:50
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:57
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:26:59
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:01:52
User entered '2'	System	12 Nov 2020 20:22:21
User entered empty.	System	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:01:52
User entered '1'	System	12 Nov 2020 20:22:21
User entered empty.	System	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:01:52
User entered '804 (804)'	System	12 Nov 2020 20:22:21
User entered empty.	System	30 Oct 2020 14:57:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:27:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:05:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:05:47
Data point term sent to Coder	System	17 Nov 2020 15:05:21
User entered 'LACTATED RINGERS'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:27:12
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:27:15
User entered 'HYPOTENSION'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:27:57
User entered '1000'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:14
User entered 'mL (mL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:17
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:21
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:26
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:32
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:34
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:37
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:39
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:40
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User entered empty.	System	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User entered empty.	System	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:15
User entered empty.	System	17 Nov 2020 15:04:30

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:05:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:05:46
Data point term sent to Coder	System	17 Nov 2020 15:05:21
User entered 'LACTATED RINGERS'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:57
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:28:59
User entered 'HYPOTENSION'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:02
User entered '750'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:04
User entered 'mL (mL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:08
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:09
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:11
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:14
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:15
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:18
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:22
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:23
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:25
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:28
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User entered empty.	System	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User entered empty.	System	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:23
User entered empty.	System	17 Nov 2020 15:05:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE TARTRATE, PRODUCTSYNONYM: CHANTIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:06:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:06:48
Data point term sent to Coder	System	17 Nov 2020 15:06:22
User entered 'CHANTIX'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:50
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:00:36
(Site from DM).		
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:25:30
' answered with 'MEDICAL HISTORY UPDATED TO INCLUDE TOBACCO UISE' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4), (b) (6)	14 Dec 2020 03:03:55
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:29:53
User entered 'SMOKING CESSATION'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:55
User entered '0.5'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:29:57
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:03
User entered 'twice daily (BID)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:04
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:08
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:10
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:12
User entered '21 Sep 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:16
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:18
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:21
User entered '21 Oct 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:23
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User entered '2'	System	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User entered '1'	System	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:27
User entered '804 (804)'	System	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:04:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:04:51
Data point term sent to Coder	System	17 Nov 2020 15:07:23
User entered 'ALBUTEROL 90MCG/ACTUATION'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:36
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:39
User entered 'ASTHMA/COPD'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:42
User entered '2'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:44
User entered 'puff (PUFF)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:48
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:47
User entered 'as needed (PRN)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:54
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:30:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:00
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:02
User entered 'I'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:05
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:08
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:06:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:10:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:10:52
Data point term sent to Coder	System	17 Nov 2020 15:08:26
User entered 'SYMBICORT 160-4.5MCG/ACTUATION'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:20
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:22
User entered 'ASTHMA/COPD'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:25
User entered '2'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:27
User entered 'puff (PUFF)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:32
User entered 'twice daily (BID)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:42
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:44
User entered 'I'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:47
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:31:55
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 15:07:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: CHOLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:45:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:45:52
Data point term sent to Coder Coding entries removed.	System Amanda Horn (b) (4) (b) (4)	17 Nov 2020 16:44:40 17 Nov 2020 16:43:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: CHOLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:09:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:09:53
Data point term sent to Coder User entered 'CHOLECALCIFEROL'	System Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:24 17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:54:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Un-verified.	(b) (4)	14 Dec 2020 17:23:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4)	14 Dec 2020 17:23:10
DataPoint Verified.	(b) (4)	17 Nov 2020 20:32:11
User entered 'No (N)'	Amanda Horn (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:24:47
' (Site from DM).		
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:25:44
' answered with 'UPDATED' (Site from DM).		
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	14 Dec 2020 03:06:55
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:32:15
User entered 'SUPPLEMENT' reason for change:	Amanda Horn (b) (4)	17 Nov 2020 16:43:39
Data Entry Error	(b) (4)	
User entered 'VITAMIN D DEFICIENCY'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:17
User entered '400'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:54:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query "Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 05:52:37
Query "Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' answered with 'CORRECTED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:20:52
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:20:29
User entered 'IU (IU)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	30 Nov 2020 22:20:29
User opened query "Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 14:15:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:32:19
User entered 'Other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:54:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Un-verified.	(b) (4)	
	Amanda Horn (b) (4)	30 Nov 2020 22:20:29
User entered empty; reason for change Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	30 Nov 2020 22:20:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:32:21
User entered 'UNITS'	Amanda Horn (b) (4)	17 Nov 2020 15:08:17
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:30
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:40
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:42
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:46
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:50
User entered 'I'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:56
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:59
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:33:02
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 15:08:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:10:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:10:51
Data point term sent to Coder	System	17 Nov 2020 15:09:27
User entered 'GABAPENTIN'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:13
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 11:17:08
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'UPDATED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:28:18
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 03:07:11
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:17
User entered 'CHRONIC BACK PAIN'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:19
User entered '800'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:21
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:34
User entered 'twice daily (BID)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:37
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:44
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:47
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:55
User entered 'I'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:34:59
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:35:04
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:35:07
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 15:09:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SLEEP APNEA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:11:56
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SLEEP APNEA should be recorded, and update con med indication or provide clarification. ' answered with 'insomnia has been preent' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 14:39:59
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SLEEP APNEA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:57:04
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:25:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:25:52
Data point term sent to Coder	System	17 Nov 2020 15:10:27
User entered 'AMBIEN'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:35:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:35:32
User entered 'SLEEP APNEA'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:35:43
User entered '10'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:35:45
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:35:48
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:01
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:15
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:19
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:22
User entered '19 Oct 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:29
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:38
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 15:09:39

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:11:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:11:54
Data point term sent to Coder	System	17 Nov 2020 15:11:28
User entered 'LACTATED RINGERS'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:57
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:01
User entered 'COVID-19'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:09
User entered 'mL (mL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:11
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:14
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:16
User entered 'PER HOUR'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:19
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:30
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:31
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:35
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:37
User entered '13 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:39
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User entered empty.	System	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User entered empty.	System	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:31
User entered empty.	System	17 Nov 2020 15:10:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:07:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:07:51
Data point term sent to Coder	System	17 Nov 2020 15:11:29
User entered 'FENTANYL'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:53
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:55
User entered 'COVID 19'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:37:56
User entered '25'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:00
User entered 'Other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:04
User entered 'MCG'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:07
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:09
User entered 'HOURLY AS NEEDED'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:19
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:21
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:25
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:30
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:33
User entered '13 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:36
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User entered empty.	System	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User entered empty.	System	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:39
User entered empty.	System	17 Nov 2020 15:11:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:07:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:07:47
Data point term sent to Coder	System	17 Nov 2020 15:12:30
User entered 'CYCLOBENZAPRINE'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:54
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:56
User entered 'COVID-19'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:38:58
User entered '5'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:01
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:03
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:05
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:07
User entered 'THREE TIMES DAILY AS NEEDED'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:11
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:15
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:40
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:42
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:46
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:48
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:39:50
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User entered empty.	System	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User entered empty.	System	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:42
User entered empty.	System	17 Nov 2020 15:12:22

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:07:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:07:47
Data point term sent to Coder	System	17 Nov 2020 15:13:32
User entered 'CYCLOBENZAPRINE'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:04
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:06
User entered 'COVID-19'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:09
User entered '10'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:11
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:15
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:18
User entered 'THREE TIMES DAILY AS NEEDED'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:20
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:25
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:41:07
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:41:11
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:41:16
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:41:19
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:13:08

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:41:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:17:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:17:48
Data point term sent to Coder	System	17 Nov 2020 15:15:36
User entered 'INSULIN [REGULAR]'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:41:39
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:41:42
User entered 'TYPE II DIABETES MELLITUS'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:41:49
User entered '0-14'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:41:51
User entered 'Other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:42:10
User entered 'UNITS'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:42:15
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:42:17
User entered 'FOUR TIMES PER DAY'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:42:24
User entered 'Subcutaneous (SUBCUTANEOUS)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:42:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:42:40
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:42:43
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:42:50
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:42:57
User entered '13 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:42:59
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User entered empty.	System	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User entered empty.	System	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:47
User entered empty.	System	17 Nov 2020 15:15:28

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:22
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)	17 Nov 2020 15:16:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:16:46
Data point term sent to Coder	System	17 Nov 2020 15:16:36
User entered 'ACETAMINOPHEN'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:26
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:29
User entered 'COVID-19'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:32
User entered '650'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:34
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:37
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:41
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:44
User entered 'EVERY 6 HOURS AS NEEDED'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:47
User entered 'Rectal (RECTAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:56
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:43:59
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:44:04
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:44:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:44:11
User entered '13 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:44:15
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User entered empty.	System	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User entered empty.	System	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:29:56
User entered empty.	System	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:44:37
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)	17 Nov 2020 15:18:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:18:46
Data point term sent to Coder	System	17 Nov 2020 15:17:37
User entered 'ACETAMINOPHEN'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:44:39
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:44:40
User entered 'COVID-19'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:44:42
User entered '1000'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:44:57
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:45:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:45:06
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:45:08
User entered 'EVERY 6 HOURS AS NEEDED'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:45:10
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:45:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:45:14
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:45:17
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:45:19
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:45:21
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:45:23
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:44:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:16:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:16:49
Data point term sent to Coder	System	17 Nov 2020 15:18:38
User entered 'KETOROLAC'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:02
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:05
User entered 'COVID-19'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:08
User entered '10'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:10
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:16
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:19
User entered 'EVERY 6 HOURS AS NEEDED'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:22
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:24
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:29
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:30
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:38
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:41
User entered '13 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:42
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User entered empty.	System	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User entered empty.	System	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:01
User entered empty.	System	17 Nov 2020 15:17:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:16:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:16:53
Data point term sent to Coder	System	17 Nov 2020 15:18:38
User entered 'KETOROLAC'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:57
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:59
User entered 'COVID- 19'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:03
User entered '20'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:06
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:10
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:12
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:13
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:17
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:19
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:25
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:35
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:37
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:41
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User entered empty.	System	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User entered empty.	System	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:04
User entered empty.	System	17 Nov 2020 15:18:19

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:13:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:13:48
Data point term sent to Coder	System	17 Nov 2020 15:19:38
User entered 'MORPHINE'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:46:54
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:00
User entered 'COVID-19'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:05
User entered '2'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:06
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:08
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:12
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:14
User entered 'EVERY 6 HOURS AS NEEDED'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:16
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:19
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:22
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:24
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:30
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:31
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User entered empty.	System	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User entered empty.	System	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User entered empty.	System	17 Nov 2020 15:19:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:41
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)	17 Nov 2020 15:21:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:21:47
Data point term sent to Coder	System	17 Nov 2020 15:20:40
User entered 'ACETAMINOPHEN'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:43
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM#22 ACETAMINOPHEN (11NOV2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 01:50:21
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM#22 ACETAMINOPHEN (11NOV2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'CM#22 ROUTE IS RECTAL WHILE THIS ENTRY IS ORAL' (Site from DM).	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:29:43
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM#22 ACETAMINOPHEN (11NOV2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 03:09:43
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:47:46
User entered 'COVID-19'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:48
User entered '650'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:50
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:51
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:54
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:59
User entered 'EVERY 6 HOURS AS NEEDED'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:48:01
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:48:03
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:48:07
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:48:42
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:49:05
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:49:08
User entered '13 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:49:10
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User entered empty.	System	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User entered empty.	System	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User entered empty.	System	17 Nov 2020 15:20:11

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:50:42
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:20:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:20:48
Data point term sent to Coder	System	17 Nov 2020 15:21:41
User entered 'ALEVE'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:50:45
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:50:47
User entered 'COVID-19'	Amanda Horn (b) (4)	17 Nov 2020 15:20:47
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:50:49
User entered '440'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:50:53
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:50:56
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:51:07
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:51:11
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:51:14
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:51:20
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:51:24
User entered '13 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:51:28
User entered '0'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:51:29
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:51:33
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:51:35
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: VERAPAMIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Feb 2021 13:42:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 13:42:41
Data point term sent to Coder	System	04 Feb 2021 19:10:52
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 19:10:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: VERAPAMIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 19:22:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 19:22:57
Data point term sent to Coder	System	25 Jan 2021 19:21:50
User entered 'verapamil'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 19:21:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4)	25 Jan 2021 19:21:37
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'INTRACTABLE HEADACHE'	(b) (4)	04 Feb 2021 19:10:35
reason for change: Data Entry Error	Amanda Horn (b) (4)	
User entered 'headaches'	(b) (4)	
	Jamie Pettus (b) (4)	25 Jan 2021 19:21:37
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '120'	(b) (4)	25 Jan 2021 19:21:37
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'mg (mg)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 19:21:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	25 Jan 2021 19:21:37
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'once daily (QD)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 19:21:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	25 Jan 2021 19:21:37
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Oral (ORAL)'	(b) (4)	25 Jan 2021 19:21:37
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	25 Jan 2021 19:21:37
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '13 Jan 2021'	(b) (4) Jamie Pettus (b) (4)	25 Jan 2021 19:21:37
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 19:21:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Yes (Y)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 19:21:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4) Jamie Pettus (b) (4)	25 Jan 2021 19:21:37
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4)	25 Jan 2021 19:21:37
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:21:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:21:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 19:21:37

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	04 Feb 2021 22:54:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:54:32
Data point term sent to Coder	System	04 Feb 2021 21:21:10
User entered 'metoclopramide'	Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Yes (Y)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'prevention of nausea related to anesthesia'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '10'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'mg (mg)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:20:41
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'once (ONCE)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:20:41
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Oral (ORAL)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:20:41
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '22 Jan 2021'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 21:20:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 21:20:59
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	04 Feb 2021 21:20:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 21:20:41
User entered empty.	System	04 Feb 2021 21:20:41
	Jamie Pettus (b) (4)	04 Feb 2021 21:20:41
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '22 Jan 2021'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User entered empty.	System	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User entered empty.	System	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User entered empty.	System	04 Feb 2021 21:20:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 22:55:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:55:30
Data point term sent to Coder	System	04 Feb 2021 21:23:11
User entered 'midazolam'	Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Yes (Y)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'prevention of anxiety related to procedure'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'l'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'mg (mg)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:22:54
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'once (ONCE)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:22:54
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:22:54
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '22 Jan 2021'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '22 Jan 2021'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
User entered empty.	System	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
User entered empty.	System	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:23
User entered empty.	System	04 Feb 2021 21:22:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ONDANSETRON HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 21:28:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 21:28:29
Data point term sent to Coder	System	04 Feb 2021 21:28:16
User entered 'ondansetron HCL'	Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Yes (Y)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'prevention of anesthesia related nausea'	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:28:05
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '4'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'mg (mg)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:28:05
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'once (ONCE)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:28:05
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:28:05
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '22 Jan 2021'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '22 Jan 2021'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
User entered empty.	System	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
User entered empty.	System	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
User entered empty.	System	04 Feb 2021 21:28:05

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 21:30:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 21:30:27
Data point term sent to Coder	System	04 Feb 2021 21:30:17
User entered 'oxycodone'	Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'post procedure pain'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '10'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'mg (mg)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:29:34
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'as needed (PRN)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:29:34
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Oral (ORAL)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:29:34
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '23 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:34:38
User entered '22 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:29:34
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '23 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:34:38
User entered '22 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:29:34
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
User entered empty.	System	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
User entered empty.	System	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:30
User entered empty.	System	04 Feb 2021 21:29:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 23:04:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 23:04:35
Data point term sent to Coder	System	04 Feb 2021 21:31:18
User entered 'oxycodone'	Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'post procedural pain'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '5'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'mg (mg)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:30:42
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'as needed (PRN)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:30:42
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Oral (ORAL)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	04 Feb 2021 21:30:42
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '22 Jan 2021'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 21:31:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 21:31:07
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	04 Feb 2021 21:31:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 21:30:42
User entered empty.	System	04 Feb 2021 21:30:42
	Jamie Pettus (b) (4)	04 Feb 2021 21:30:42
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '02 Feb 2021' reason for change: Data Entry Error	Jamie Pettus (b) (4)	04 Feb 2021 21:35:14
	(b) (4)	
User entered '22 Jan 2021'	Jamie Pettus (b) (4)	04 Feb 2021 21:30:42
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
User entered empty.	System	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
User entered empty.	System	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:41
User entered empty.	System	04 Feb 2021 21:30:42

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: RAMIPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Feb 2021 11:52:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 11:52:45
Data point term sent to Coder User entered 'ramapril'	System Jamie Pettus (b) (4) (b) (4)	08 Feb 2021 15:13:41 08 Feb 2021 15:13:15

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4)	08 Feb 2021 15:13:15
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'entered AE' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:48:04
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). User signature succeeded.	Jamie Pettus (b) (4)	09 Mar 2021 20:00:17
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	04 Mar 2021 16:30:59
User entered 'hypertension'	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:02:47
	Jamie Pettus (b) (4)	08 Feb 2021 15:13:15

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'per source, dose =120. please clarify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:00:42
Query 'per source, dose =120. please clarify' answered with '10 mg is the correct dosage for Ramapril. Updated' (Site from CRA).	Haylee Rowe (b) (4)	20 Apr 2021 17:00:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User opened query 'per source, dose =120. please clarify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:58:20
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
	(b) (4)	
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 17:06:28
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Jamie Pettus (b) (4)	09 Mar 2021 20:00:23
Signature has been broken.	(b) (4)	
User entered '10' reason for change: Data Entry Error	Jamie Pettus (b) (4)	09 Mar 2021 20:00:05
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	04 Mar 2021 16:31:05
	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '120'	Jamie Pettus (b) (4)	08 Feb 2021 15:13:15
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'mg (mg)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	08 Feb 2021 15:13:15

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	08 Feb 2021 15:13:15
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'once daily (QD)'	Jamie Pettus	08 Feb 2021 15:13:15

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	08 Feb 2021 15:13:15
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Oral (ORAL)'	(b) (4)	08 Feb 2021 15:13:15
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	08 Feb 2021 15:13:15
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 18:00:38
User closed query 'per source, date =13Jan2021. please clarify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:00:35
Query 'per source, date =13Jan2021. please clarify' answered with 'Corrected date' (Site from CRA).	Haylee Rowe (b) (4)	20 Apr 2021 17:02:07
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	20 Apr 2021 17:01:39
	(b) (4)	
User entered '13 Jan 2021' reason for change: Data Entry Error	Haylee Rowe (b) (4)	20 Apr 2021 17:01:39
	(b) (4)	
User opened query 'per source, date =13Jan2021. please clarify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:00:05
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:56
	(b) (4), (b) (6)	
Query 'per source, dare =13Jan2021. please clarify' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:59:54
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
	(b) (4), (b) (6)	
User opened query 'per source, dare =13Jan2021. please clarify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:58:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '19 Jan 2021'	Jamie Pettus (b) (4)	08 Feb 2021 15:13:15
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	08 Feb 2021 15:13:15

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'Yes (Y)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	08 Feb 2021 15:13:15

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	08 Feb 2021 15:13:15
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'No (N)'	(b) (4)	08 Feb 2021 15:13:15
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 15:13:15

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 15:13:15

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Feb 2021 15:13:15

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CANNABIS SATIVA, PRODUCTSYNONYM: MARIJUANA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 10:22:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 10:22:41
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:12:20
Data point term sent to Coder	System	09 Mar 2021 20:04:54
User entered 'MEDICAL MARIJUANA'	Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'CHRONIC PAIN PREVENTION'	Haylee Rowe (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'UNKNOWN'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Other (OTHER)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'UNKNOWN'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:04:13
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'once daily (QD)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:04:13
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 20:04:13
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '22 Feb 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	Haylee Rowe (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:04:13
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 20:04:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIDIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:51:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:51:40
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:12:20
Data point term sent to Coder	System	09 Mar 2021 20:05:55
User entered 'CBD HARD CANDY EDIBLES'	Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:05:00

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:05:00

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'CHRONIC PAIN PREVENTION'	Haylee Rowe (b) (4)	09 Mar 2021 20:05:00

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '5'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:05:00

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'mg (mg)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:05:00

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 20:05:00
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'three times daily (TID)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	09 Mar 2021 20:05:00

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 20:05:00
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Oral (ORAL)'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:05:00
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	09 Mar 2021 20:05:00
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '22 Feb 2021'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:05:00
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '0'	Haylee Rowe (b) (4)	09 Mar 2021 20:05:00

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'Yes (Y)'	(b) (4)	09 Mar 2021 20:05:00
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:05:00
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:42
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'No (N)'	(b) (4)	
	Haylee Rowe (b) (4)	09 Mar 2021 20:05:00
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	09 Mar 2021 20:05:00

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 20:05:00

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 20:05:00

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:25:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:25:49
User signature succeeded.	Priyantha Wijewardane (b) (4)	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:14:34
Data point term sent to Coder	System	20 Apr 2021 17:18:02
User entered 'INSULIN, REGULAR'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'TYPE II DIABETES MELLITUS'	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '4'	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'IU (IU)'	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'once (ONCE)'	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '23 Jan 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '0'	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '23 Jan 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:17:36
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User entered empty.	System	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User entered empty.	System	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:45
User entered empty.	System	20 Apr 2021 17:17:36

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 18:37:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 18:37:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:14:34
Data point term sent to Coder	System	20 Apr 2021 17:19:03
User entered '0.99% NACL'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'PREVENTION OF FLUID IMBALANCE'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '100'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'Other (OTHER)'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'ML/HR'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'other (OTHER)'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'CONTINUOUS INFUSION'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '22 Jan 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '0'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '23 Jan 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:18:54
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User entered empty.	System	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User entered empty.	System	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:55
User entered empty.	System	20 Apr 2021 17:18:54

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
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)	20 Apr 2021 17:20:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:20:38
Data point term sent to Coder	System	20 Apr 2021 17:20:04
User entered 'ACETAMINOPHEN'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'POST PROCEDURE PAIN'	Haylee Rowe (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '1000'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'mg (mg)'	Haylee Rowe (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'once (ONCE)'	Haylee Rowe (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '22 Jan 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '0'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '22 Jan 2021'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User entered empty.	System	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User entered empty.	System	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User entered empty.	System	20 Apr 2021 17:19:41

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
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)	20 Apr 2021 17:21:29
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 Apr 2021 17:21:29
Data point term sent to Coder	System	20 Apr 2021 17:21:06
User entered 'ACETAMINOPHEN'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:20:38
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'POST PROCEDURE PAIN'	Haylee Rowe (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '650'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'mg (mg)'	Haylee Rowe (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'as needed (PRN)'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '22 Jan 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '0'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '02 Feb 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User entered empty.	System	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User entered empty.	System	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:00
User entered empty.	System	20 Apr 2021 17:20:38

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:34:32
User closed query 'Docusate sodium per Medical records. please review and clarify' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:34:20
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Apr 2021 19:50:43
Query 'Docusate sodium per Medical records. please review and clarify' answered with 'data updated per query' (Site from CRA).	(b) (4)	
Data point term sent to Coder	Lauren Evans (b) (4)	20 Apr 2021 18:29:23
User entered 'DOCUSATE SODIUM' reason for change: Data Entry Error	System	20 Apr 2021 18:29:13
DataPoint Un-verified.	Lauren Evans (b) (4)	20 Apr 2021 18:29:01
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	20 Apr 2021 18:14:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User opened query 'Docusate sodium per Medical records. please review and clarify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:14:25
Data point term sent to Coder	System	20 Apr 2021 17:22:06
User entered 'DOCUGATE SODIUM'	Haylee Rowe (b) (4)	20 Apr 2021 17:21:34
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	20 Apr 2021 17:21:34
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'PREVENTION OF CONSTIPATION'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '100'	Haylee Rowe (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'mg (mg)'	Haylee Rowe (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'twice daily (BID)'	Haylee Rowe (b) (4)	20 Apr 2021 17:21:34
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '22 Jan 2021'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '0'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '02 Feb 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User entered '2'	System	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User entered '1'	System	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:03
User entered '804 (804)'	System	20 Apr 2021 17:21:34

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 20:16:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:14:34
Data point term sent to Coder	System	20 Apr 2021 17:23:07
User entered 'HYDROMORPHONE'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'PAIN PREVENTION'	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '0.5'	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'mg (mg)'	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'once (ONCE)'	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'Intravenous (INTRAVENOUS)'	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '22 Jan 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '0'	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '22 Jan 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User entered empty.	System	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User entered empty.	System	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User entered empty.	System	20 Apr 2021 17:22:20

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 21:03:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:03:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:14:34
Data point term sent to Coder	System	20 Apr 2021 17:23:07
User entered 'KETORLAC'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'PAIN PREVENTION'	Haylee Rowe (b) (4)	20 Apr 2021 17:23:04
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '15'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'mg (mg)'	Haylee Rowe (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'once (ONCE)'	Haylee Rowe (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'Intravenous (INTRAVENOUS)'	Haylee Rowe (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '22 Jan 2021'	Haylee Rowe (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered '0'	Haylee Rowe (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered '22 Jan 2021'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:34
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User entered empty.	System	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User entered empty.	System	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:09
User entered empty.	System	20 Apr 2021 17:23:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 19:40:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:40:41
Data point term sent to Coder	System	20 Apr 2021 19:37:25
User entered 'CELECOXIB'	Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 19:37:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered 'No (N)'	(b) (4)	20 Apr 2021 19:37:04
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered 'INCREASED PAIN IN RIGHT KNEE'	(b) (4)	
	Haylee Rowe (b) (4)	20 Apr 2021 19:37:04
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered '200'	(b) (4) Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 19:37:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered 'mg (mg)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 19:37:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered empty.	(b) (4)	20 Apr 2021 19:37:04
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered 'once daily (QD)'	Haylee Rowe (b) (4)	20 Apr 2021 19:37:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered empty.	(b) (4)	20 Apr 2021 19:37:04
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4)	20 Apr 2021 19:37:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered empty.	(b) (4)	20 Apr 2021 19:37:04
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered '31 Mar 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	20 Apr 2021 19:37:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered '0'	Haylee Rowe	20 Apr 2021 19:37:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Haylee Rowe (b) (4)	20 Apr 2021 19:37:10
User entered 'No (N)'	(b) (4)	
	Haylee Rowe (b) (4)	20 Apr 2021 19:37:04
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).	(b) (4)	20 Apr 2021 19:37:10
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		20 Apr 2021 19:37:04
User entered empty.	Haylee Rowe (b) (4)	20 Apr 2021 19:37:04
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:01:32
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
User entered 'No (N)'	(b) (4)	20 Apr 2021 19:37:04
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:37:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:37:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 19:37:04

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:44:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:44:56
User signature succeeded.	Priyantha Wijewardane (b) (4)	23 Apr 2021 23:36:01
Data point term sent to Coder System	System	23 Apr 2021 19:26:35
User entered 'TORADOL'	Haylee Rowe (b) (4) (b) (4)	23 Apr 2021 19:26:07

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'RIGHT KNEE ARTHROSCOPY PAIN MANAGEMENT'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '15'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'mg (mg)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'once (ONCE)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '23 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '23 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:07
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:26:07

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:26:07

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:26:07

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:35:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:35:52
User signature succeeded.	Priyantha Wijewardane (b) (4)	23 Apr 2021 23:36:01
Data point term sent to Coder	System	23 Apr 2021 19:27:36
User entered 'OXYCODONE'	Haylee Rowe (b) (4) (b) (4)	23 Apr 2021 19:26:50

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'RIGHT KNEE ARTHROSCOPY PAIN MANAGEMENT'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '5'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'mg (mg)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'once (ONCE)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '23 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '23 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:26:50
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:26:50

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:26:50

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:26:50

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ONDANSETRON HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 19:27:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 19:27:56
Data point term sent to Coder	System	23 Apr 2021 19:27:36
User entered 'ONDANSETRON HCL'	Haylee Rowe (b) (4) (b) (4)	23 Apr 2021 19:27:35

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'NAUSEA PREVENTION'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '4'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'mg (mg)'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'once (ONCE)'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '23 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '23 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:27:35
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:27:35

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:27:35

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:27:35

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
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: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 09:59:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 09:59:39
User signature succeeded.	Priyantha Wijewardane (b) (4)	23 Apr 2021 23:36:01
Data point term sent to Coder	System	23 Apr 2021 19:29:39
User entered 'CEFAZOLIN IN STERILE WATER'	Haylee Rowe (b) (4) (b) (4)	23 Apr 2021 19:29:26

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'INFECTION PREVENTION'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '2/20'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Other (OTHER)'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'G/ML'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'once (ONCE)'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '23 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '23 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:29:26
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:29:26

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:29:26

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:29:26

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 13:53:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 13:53:02
User signature succeeded.	Priyantha Wijewardane (b) (4)	23 Apr 2021 23:36:01
Data point term sent to Coder	System	23 Apr 2021 19:32:42
Coding entries removed.	Haylee Rowe (b) (4)	23 Apr 2021 19:31:50
User entered 'VITAMIN D3 (CHOLECALCIFEROL)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	23 Apr 2021 19:31:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 19:31:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 19:31:17
Data point term sent to Coder	System	23 Apr 2021 19:30:40
User entered 'VITAMIN D3'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'BONE HEALTH'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '400'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'IU (IU)'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'once daily (QD)'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'UN Mar 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:30:06
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 19:30:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 19:30:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 19:30:06

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:32:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:32:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	23 Apr 2021 23:36:01
Data point term sent to Coder	System	23 Apr 2021 19:31:42
User entered 'NORCO (HYDROCODONE-ACETAMINOPHEN)'	Haylee Rowe (b) (4) (b) (4)	23 Apr 2021 19:31:12

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'POST-PROCEDURE PAIN'	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '10-325'	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'mg (mg)'	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'once daily (QD)'	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '23 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:31:12
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 19:31:12

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 19:31:12

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 19:31:12

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: METOCLOPRAMIDE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 19:34:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 19:34:04
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 19:33:44
User entered 'METOCLOPRAMIDE HCL'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'PRE/POST ANESTHESIA NAUSEA PREVENTION'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '10'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'mg (mg)'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'once daily (QD)'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '10 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '0'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'No (N)'	Haylee Rowe (b) (4)	23 Apr 2021 19:32:45
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 19:32:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 19:32:45

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:41:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 19:32:45

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:41:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:37:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:16:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 16:12:17

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:41:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:16:17
User entered '10 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:30:49

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:41:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:16:17
User entered 'CHEST XRAY 1 VIEW PORTABLE AP'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:30:49

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:16:17
User entered 'Adverse Event (AE)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:30:49

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:41:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:16:17
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:30:49

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:41:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Source says start date was 10NOV2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:14:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:14:46
Query 'Source says start date was 10NOV2020' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:02:23
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:02:16
User opened query 'Source says start date was 10NOV2020' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:17:15
User entered '11 Nov 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:31:12

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:41:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:17:20
User entered 'CT HEAD WITHOUT CONTRAST'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:31:12

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:17:22
User entered 'Adverse Event (AE)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:31:12

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:41:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:17:24
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 15:31:12

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:41:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:17:43
User entered '21 Oct 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 16:32:17

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:41:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:17:51
User entered 'CT CHEST WITHOUT CONTRAST'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 16:32:17

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:01:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:25:58
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 16:25:58
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:17:54
User entered 'Medical History (MH)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 16:32:17

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:41:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:18:02
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 16:32:17

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:41:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:18:21
User entered '21 Oct 2020'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 16:32:51

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:41:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:18:24
User entered 'MYOCARDIAL PERFUSION/PHARMACOLOGIC STRESS TEST'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 16:32:51

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:14
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:01:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Jan 2021 12:45:58
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 16:25:17
DataPoint Un-verified.	(b) (4), (b) (6)	28 Dec 2020 16:25:09
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 16:25:09
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:35:07
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:18:27
User entered 'Medical History (MH)'	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 16:32:51

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:41:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:18:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	17 Nov 2020 16:32:51

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:41:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:01:30
User closed query 'Per ETRTR: Procedure was performed on 22Jan21 related to SAE "CLEAR CELL RENAL CARCINOMA". Please go to SAE page and tick within "Concomitant Procedures" Action Taken checkbox, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 15:33:04
Query 'Per ETRTR: Procedure was performed on 22Jan21 related to SAE "CLEAR CELL RENAL CARCINOMA". Please go to SAE page and tick within "Concomitant Procedures" Action Taken checkbox, thanks' answered with 'done' (Site from CRA).	Jamie Pettus (b) (4) (b) (4)	01 Mar 2021 19:25:15
User opened query 'Per ETRTR: Procedure was performed on 22Jan21 related to SAE "CLEAR CELL RENAL CARCINOMA". Please go to SAE page and tick within "Concomitant Procedures" Action Taken checkbox, thanks' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 17:43:02
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:02:47
User entered '22 Jan 2021' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	04 Feb 2021 19:01:22
User entered '15 Jan 2021'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 19:22:54

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:41:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:01:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'ROBOTIC ASSISTED	(b) (4)	
LAPAROSCOPIC LEFT RETROPERITONEAL	Amanda Horn (b) (4)	04 Feb 2021 19:01:22
PARTIAL NEPHRECTOMY' reason for change:	(b) (4)	
Data Entry Error		
User entered 'laparoscopic partial nephrectomy'	Jamie Pettus (b) (4)	25 Jan 2021 19:22:54
	(b) (4)	

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:19
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:12:45
DataPoint Verified.	(b) (4)	20 Apr 2021 18:16:38
User closed query 'per source, it states Medical history please clarify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:16:35
Query 'per source, it states Medical history please clarify' answered with 'Corrected to medical history' (Site from CRA).	Haylee Rowe (b) (4)	20 Apr 2021 17:03:59
Signature has been broken.	(b) (4)	
User entered 'Medical History (MH)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	20 Apr 2021 17:03:31
User opened query 'per source, it states Medical history please clarify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:02:19
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
Signature has been broken.	(b) (4)	
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Mar 2021 19:25:09
User signature succeeded.	(b) (4)	
User entered 'Medical History (MH)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Mar 2021 19:25:09
User entered 'Adverse Event (AE)'	(b) (4)	
	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
	Amanda Horn (b) (4)	04 Feb 2021 19:01:22
	(b) (4)	
	Jamie Pettus (b) (4)	25 Jan 2021 19:22:54
	(b) (4)	

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:41:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:16:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	25 Jan 2021 19:22:54
	(b) (4)	

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:41:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:02:34
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:40:31

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:41:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:02:36
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'MRI of right knee'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:40:31

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:02:38
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
User closed query 'Per CDM: Please consider changing Other to Adverse Event. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:56:51
Query 'Per CDM: Please consider changing Other to Adverse Event. Thank you.' answered with 'Corrected' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	12 Apr 2021 13:13:54
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	12 Apr 2021 13:13:27
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	12 Apr 2021 13:13:27
User opened query 'Per CDM: Please consider changing Other to Adverse Event. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 14:23:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	08 Apr 2021 13:38:56
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	07 Apr 2021 17:41:18
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:41:18
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	07 Apr 2021 17:40:31
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	07 Apr 2021 17:40:31

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:41:55

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:02:40
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
Signature has been broken.	(b) (4)	12 Apr 2021 13:13:27
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4)	12 Apr 2021 13:13:27
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:56
User entered 'Adverse Event - increased pain in right knee' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:41:18
User entered 'increased pain in right knee'	(b) (4), (b) (6)	07 Apr 2021 17:40:31

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:41:55

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered '23 Apr 2021'	Haylee Rowe (b) (4)	23 Apr 2021 18:42:42
	(b) (4)	

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:41:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'ATHROSCOPY OF RIGHT KNEE'	Haylee Rowe (b) (4)	23 Apr 2021 18:42:42
	(b) (4)	

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:41:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered 'Adverse Event (AE)'	Haylee Rowe (b) (4)	23 Apr 2021 18:42:42
	(b) (4)	

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:41:55

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:01
	(b) (4)	
User entered empty.	Haylee Rowe (b) (4)	23 Apr 2021 18:42:42
	(b) (4)	

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:38
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'USA-US113-2020-MRNA-1273-P301000013'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:02
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:43
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:47
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:54
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Priyantha'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:55
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Wijewardane'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4)	18 Nov 2020 13:38:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:21:59
User entered 'US'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '6'	System	15 Dec 2020 17:15:09
User entered '5'	System	24 Nov 2020 14:31:18
User entered '4'	System	21 Nov 2020 15:15:16
User entered '3'	System	18 Nov 2020 13:38:26
User entered '2'	System	17 Nov 2020 01:02:10
User entered '1'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:38
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'USA-US113-2020-MRNA-1273-P301000013'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:02
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:43
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	16 Nov 2020 17:21:47
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:49:25
	System	

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:54
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Priyantha'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:55
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Wijewardane'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4)	18 Nov 2020 13:38:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:21:59
User entered 'US'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '6'	System	15 Dec 2020 17:15:09
User entered '5'	System	24 Nov 2020 14:31:18
User entered '4'	System	21 Nov 2020 15:15:16
User entered '3'	System	18 Nov 2020 13:38:26
User entered '2'	System	17 Nov 2020 01:02:10
User entered '1'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	16 Nov 2020 17:22:08
	(b) (4), (b) (6)	
User entered '13/Nov/2020 15:51'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:41:55

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 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:38:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:22:10
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:38
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'USA-US113-2020-MRNA-1273-P301000013'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:02
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:43
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:47
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:54
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Priyantha'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:55
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Wijewardane'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4)	18 Nov 2020 13:38:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:21:59
User entered 'US'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '6'	System	15 Dec 2020 17:15:09
User entered '5'	System	24 Nov 2020 14:31:18
User entered '4'	System	21 Nov 2020 15:15:16
User entered '3'	System	18 Nov 2020 13:38:26
User entered '2'	System	17 Nov 2020 01:02:10
User entered '1'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	17 Nov 2020 20:05:56
	(b) (4), (b) (6)	
User entered '17/Nov/2020 01:02'	System	17 Nov 2020 01:02:10

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:41:55

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 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:38:14
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:06:01
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 01:02:10

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:38
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'USA-US113-2020-MRNA-1273-P301000013'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:02
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:43
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:47
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	16 Nov 2020 17:21:52
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:54
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Priyantha'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:55
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Wijewardane'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4)	18 Nov 2020 13:38:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:21:59
User entered 'US'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '6'	System	15 Dec 2020 17:15:09
User entered '5'	System	24 Nov 2020 14:31:18
User entered '4'	System	21 Nov 2020 15:15:16
User entered '3'	System	18 Nov 2020 13:38:26
User entered '2'	System	17 Nov 2020 01:02:10
User entered '1'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:20:23
User entered '18/Nov/2020 08:38'	System	18 Nov 2020 13:38:26

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:41:55

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 18:02:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:20:30
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 13:38:26

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:38
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'USA-US113-2020-MRNA-1273-P301000013'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:02
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:43
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:47
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	16 Nov 2020 17:21:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:49:25
	System	

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:54
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Priyantha'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:55
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Wijewardane'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4)	18 Nov 2020 13:38:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:21:59
User entered 'US'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '6'	System	15 Dec 2020 17:15:09
User entered '5'	System	24 Nov 2020 14:31:18
User entered '4'	System	21 Nov 2020 15:15:16
User entered '3'	System	18 Nov 2020 13:38:26
User entered '2'	System	17 Nov 2020 01:02:10
User entered '1'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:01:53
User entered '21/Nov/2020 15:15'	System	21 Nov 2020 15:15:16

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:41:55

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 18:02:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:01:53
User entered 'I'	(b) (4), (b) (6)	21 Nov 2020 15:15:16

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:38
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'USA-US113-2020-MRNA-1273-P301000013'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:02
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:43
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:47
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:21:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:54
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Priyantha'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:55
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Wijewardane'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4)	18 Nov 2020 13:38:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:21:59
User entered 'US'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '6'	System	15 Dec 2020 17:15:09
User entered '5'	System	24 Nov 2020 14:31:18
User entered '4'	System	21 Nov 2020 15:15:16
User entered '3'	System	18 Nov 2020 13:38:26
User entered '2'	System	17 Nov 2020 01:02:10
User entered '1'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '24/Nov/2020 14:31'	(b) (4)	24 Nov 2020 14:31:18

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:41:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:31:18

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:38
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'USA-US113-2020-MRNA-1273-P301000013'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:02
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:43
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Yes (Y)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4)	16 Nov 2020 17:21:47
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'No (N)'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:54
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Priyantha'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:55
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:50:56
User entered 'Wijewardane'	System	13 Nov 2020 15:49:25

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4)	18 Nov 2020 13:38:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:21:59
User entered 'US'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '6'	System	15 Dec 2020 17:15:09
User entered '5'	System	24 Nov 2020 14:31:18
User entered '4'	System	21 Nov 2020 15:15:16
User entered '3'	System	18 Nov 2020 13:38:26
User entered '2'	System	17 Nov 2020 01:02:10
User entered '1'	System	13 Nov 2020 15:51:08

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '15/Dec/2020 11:15'	(b) (4)	15 Dec 2020 17:15:09

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:41:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:15:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'USA-US113-2021-MRNA-1273-P301000005'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Priyantha'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Wijewardane'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'US'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Mar 2021 15:49:02
User entered '6'	System	19 Mar 2021 14:40:34
User entered '5'	System	18 Mar 2021 15:41:48
User entered '4'	System	12 Mar 2021 14:56:32
User entered '3'	System	02 Mar 2021 17:07:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '2'	System	05 Feb 2021 15:41:20
User entered '1'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'USA-US113-2021-MRNA-1273-P301000005'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Priyantha'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Wijewardane'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'US'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Mar 2021 15:49:02
User entered '6'	System	19 Mar 2021 14:40:34
User entered '5'	System	18 Mar 2021 15:41:48
User entered '4'	System	12 Mar 2021 14:56:32
User entered '3'	System	02 Mar 2021 17:07:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '2'	System	05 Feb 2021 15:41:20
User entered '1'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '05/Feb/2021 10:40'	(b) (4)	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:41:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'USA-US113-2021-MRNA-1273-P301000005'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Priyantha'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Wijewardane'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'US'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Mar 2021 15:49:02
User entered '6'	System	19 Mar 2021 14:40:34
User entered '5'	System	18 Mar 2021 15:41:48
User entered '4'	System	12 Mar 2021 14:56:32
User entered '3'	System	02 Mar 2021 17:07:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '2'	System	05 Feb 2021 15:41:20
User entered '1'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
User entered '05/Feb/2021 10:41'	(b) (4)	05 Feb 2021 15:41:20

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:41:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 15:41:20

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'USA-US113-2021-MRNA-1273-P301000005'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Priyantha'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Wijewardane'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'US'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Mar 2021 15:49:02
User entered '6'	System	19 Mar 2021 14:40:34
User entered '5'	System	18 Mar 2021 15:41:48
User entered '4'	System	12 Mar 2021 14:56:32
User entered '3'	System	02 Mar 2021 17:07:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '2'	System	05 Feb 2021 15:41:20
User entered '1'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
User entered '02/Mar/2021 12:07'	(b) (4)	02 Mar 2021 17:07:26

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:41:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:21:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:08:06
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 17:07:26

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'USA-US113-2021-MRNA-1273-P301000005'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Priyantha'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Wijewardane'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'US'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Mar 2021 15:49:02
User entered '6'	System	19 Mar 2021 14:40:34
User entered '5'	System	18 Mar 2021 15:41:48
User entered '4'	System	12 Mar 2021 14:56:32
User entered '3'	System	02 Mar 2021 17:07:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '2'	System	05 Feb 2021 15:41:20
User entered '1'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered '12/Mar/2021 08:56'	(b) (4)	12 Mar 2021 14:56:32

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:41:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:40:09
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:12:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:56:32

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'USA-US113-2021-MRNA-1273-P301000005'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Priyantha'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Wijewardane'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'US'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Mar 2021 15:49:02
User entered '6'	System	19 Mar 2021 14:40:34
User entered '5'	System	18 Mar 2021 15:41:48
User entered '4'	System	12 Mar 2021 14:56:32
User entered '3'	System	02 Mar 2021 17:07:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '2'	System	05 Feb 2021 15:41:20
User entered '1'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:36
User entered '18/Mar/2021 08:41'	(b) (4)	18 Mar 2021 15:41:48

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:41:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:40:09
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 15:41:48

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'USA-US113-2021-MRNA-1273-P301000005'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Priyantha'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Wijewardane'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'US'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Mar 2021 15:49:02
User entered '6'	System	19 Mar 2021 14:40:34
User entered '5'	System	18 Mar 2021 15:41:48
User entered '4'	System	12 Mar 2021 14:56:32
User entered '3'	System	02 Mar 2021 17:07:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '2'	System	05 Feb 2021 15:41:20
User entered '1'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:36
User entered '19/Mar/2021 09:40'	(b) (4)	19 Mar 2021 14:40:34

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:41:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 15:43:49
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:40:34

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'USA-US113-2021-MRNA-1273-P301000005'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Yes (Y)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'No (N)'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Priyantha'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'Wijewardane'	System	05 Feb 2021 15:36:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:41:23
User entered 'US'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Mar 2021 15:49:02
User entered '6'	System	19 Mar 2021 14:40:34
User entered '5'	System	18 Mar 2021 15:41:48
User entered '4'	System	12 Mar 2021 14:56:32
User entered '3'	System	02 Mar 2021 17:07:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:02:47
	(b) (4)	
User entered '2'	System	05 Feb 2021 15:41:20
User entered '1'	System	05 Feb 2021 15:40:09

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:41:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:12:47
User entered '30/Mar/2021 11:48'	(b) (4)	30 Mar 2021 15:49:02

US3752025

Folder: SAE USA-US113-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:41:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:35
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:12:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:49:02