

US3752025 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:13:36

All time stamps listed in this document are displayed in GMT

US3752025

Form: Participant Creation

Generated On: 26 Nov 2020 11:13:36

[Participant ID](#)

US3752025

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

US3752025

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

Generated On: 26 Nov 2020 11:13:36

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 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3752025

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:13:36

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3752025

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:13:36

Were any significant conditions reported?

Yes ☒

No ☐

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:36

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:13:36

Condition	DIABETES MELLITUS TYPE II
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:13:36

Condition	GERD/REFLUX
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:13:36

Condition	SURGICAL STERILIZATION/HYSTERECTOM Y
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:13:36

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:13:36

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 ☐ No ☒
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)

Generated On: 26 Nov 2020 11:13:36

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 ☐ No ☒
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

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:36

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1978
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:36

Condition	CHOLECYSTECTOMY (ASSOCIATED CONDITION UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:13:36

Condition	AORTIC ANEURYSM
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:36

Condition	ASTHMA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
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 (12)

Generated On: 26 Nov 2020 11:13:36

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISORDER
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒ No ☐
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 (13)

Generated On: 26 Nov 2020 11:13:36

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
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 (14)

Generated On: 26 Nov 2020 11:13:36

Condition	URINARY FREQUENCY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
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 (15)

Generated On: 26 Nov 2020 11:13:36

Condition	GENERALIZED HEADACHES
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
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 (16)

Generated On: 26 Nov 2020 11:13:36

Condition	ARTHRITIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
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 (17)

Generated On: 26 Nov 2020 11:13:36

Condition	DEPRESSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
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 (18)

Generated On: 26 Nov 2020 11:13:36

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
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 (19)

Generated On: 26 Nov 2020 11:13:36

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)	

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:13:36

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐
	No ☒
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 (21)

Generated On: 26 Nov 2020 11:13:36

Condition	LAPAROSCOPIC HYSTERECTOMY FOR ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (22)

Generated On: 26 Nov 2020 11:13:36

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐
	No ☒
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)

Generated On: 26 Nov 2020 11:13:36

Condition	WISDOM TOOTH EXTRACTION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐
	No ☒
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)

Generated On: 26 Nov 2020 11:13:36

Condition	RIGHT BREAST BIOPSIES X 4
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐
	No ☒
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: Vital Signs

Generated On: 26 Nov 2020 11:13:36

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:13:36

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.

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:36

Date of assessment (<i>dd MMM yyyy</i>)	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 (<i>dd MMM yyyy</i>)	UN UNK 1989
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

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

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

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

US3752025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:36

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 ☒

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:36

Height	ND - Not Done
Weight	ND - Not Done

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	10 AUG 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 11:13:36

Collection date (<i>dd MMM yyyy</i>)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

Yes ☐	
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: 26 Nov 2020 11:13:36

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 ☒

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:36

Yes ☐	
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: 26 Nov 2020 11:13:36

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 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:36

Yes ☐	
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: 26 Nov 2020 11:13:36

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 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:36

Yes ☐	
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: 26 Nov 2020 11:13:36

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 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:36

Yes ☐	
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: 26 Nov 2020 11:13:36

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 ☒

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:36

Yes ☐	
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

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

25 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

Generated On: 26 Nov 2020 11:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

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 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 11:13:36

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

Collection date (<i>dd MMM yyyy</i>)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

Yes ☐	
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: 26 Nov 2020 11:13:36

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 ☒

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:36

Yes ☐	
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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

Yes ☐	
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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

Yes ☐	
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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

Yes ☐	
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: 26 Nov 2020 11:13:36

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 ☒

US3752025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:36

Yes ☐	
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

Generated On: 26 Nov 2020 11:13:36

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 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:10 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 10:10
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	99 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

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

[Patient Cloud Close Date & Time](#)

11 OCT 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

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

[Patient Cloud Close Date & Time](#)

18 OCT 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:13:36

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 11:13:36

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:13:36

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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: 26 Nov 2020 11:13:36

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 11:13:36

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:13:36

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:13:36

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 11:13:36

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:13:36

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 26 Nov 2020 11:13:36

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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: 26 Nov 2020 11:13:36

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 11:13:36

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 11:13:36

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:13:36

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 11:13:36

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 26 Nov 2020 11:13:36

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:13:36

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:13:36

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 11:13:36

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 11:13:36

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

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:13:36

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:13:36

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

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3752025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:13:36

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	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☒
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Cough	None ☐	
	Mild ☒	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Shortness of Breath	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Difficulty Breathing	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Fatigue	None ☒	
v6.020 DTW (1102)	353 of 3141	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	357 of 3141	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Cough	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Shortness of Breath	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Difficulty Breathing	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Fatigue	None ☒	
v6.020 DTW (1102)	361 of 3141	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:36

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

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:13:36

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:13:36

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	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☒
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	8 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	368 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	9 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	372 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	376 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	380 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:36

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	384 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	388 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	392 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:36

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	396 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:36

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	400 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:36

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	404 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	408 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	412 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:36

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	416 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:36

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☒
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	420 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☒
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	424 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☒
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	428 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☒
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:13:36

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	432 of 3141	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:13:36

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:13:36

	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	☐

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

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 _____

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 _____

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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

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 _____

Hepatic Dysfunction? Yes ☐ No ☒

Start Date _____

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

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)	

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:13:36

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		
Day 28		

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

Were vital signs assessed?	Yes ☒
	No ☐
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
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
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)	

US3752025

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:36

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.

US3752025

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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 _____

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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 _____

US3752025

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3752025

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:13:36

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)

Generated On: 26 Nov 2020 11:13:36

AEID	
Adverse event	COUGH
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)	11 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	458 of 3141

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:36

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)

Generated On: 26 Nov 2020 11:13:36

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 ☐
Number of Days in ICU	
v6.020 DTW (1102)	
460 of 3141	

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:36

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)

Generated On: 26 Nov 2020 11:13:36

AEID	USA-US113-2020-MRNA-1273-P30 1000013
Adverse event	HYPOTENSION REQUIRING HOSPITALIZATION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	13 NOV 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	True
Hospital Admission Date (dd MMM yyyy)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

462 of 3141

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

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

v6.020 DTW (1102)

463 of 3141

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

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

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

AEID	USA-US113-2020-MRNA-1273-P30 1000013
Adverse event	COVID-19
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)	08 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	465 of 3141

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☒ Unknown ☐
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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:13:36

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

Yes ☒

No ☐

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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	2 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:36

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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:36

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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:36

Name of Medication	ZOLOFT
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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intraocular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:36

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intraocular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:13:36

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		03 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		UN NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intraocular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:13:36

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:13:36

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☒
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	10 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	10 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	_____
Interval Dosage Unit Number (derived)	_____
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☒
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 10 NOV 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intraocular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:13:36

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intraocular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:13:36

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:36

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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:13:36

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	
Route of administration	PER HOUR Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☒
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intraocular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:13:36

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intraocular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:13:36

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:13:36

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	
Route of administration	EVERY 6 HOURS AS NEEDED Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:13:36

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☒
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐

If route of administration is Other, specify	

Start date (dd MMM yyyy)	11 NOV 2020

Start date completely unknown	False

Ongoing?	Yes ☐
	No ☒

If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020

Was this medication taken for solicited event?	Yes ☐
	No ☒

Separate Dosage Number (derived)	

Interval Dosage Unit Number (derived)	

Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:13:36

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	
Route of administration	EVERY 6 HOURS AS NEEDED Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:13:36

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	
Route of administration	EVERY 6 HOURS AS NEEDED Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 11 NOV 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 11:13:36

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	
Route of administration	EVERY 6 HOURS AS NEEDED Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 11:13:36

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	
Route of administration	EVERY 6 HOURS AS NEEDED Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 11:13:36

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 ☐ Intramuscular ☐

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 11:13:36

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:13:36

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:13:36

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	Medical History	
21 OCT 2020	MYOCARDIAL PERFUSION/PHARMACOLOGIC STRESS TEST	Medical History	

US3752025

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

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

Generated On: 26 Nov 2020 11:13:36

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:13:36

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5
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)

Generated On: 26 Nov 2020 11:13:36

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5
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)

Generated On: 26 Nov 2020 11:13:36

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5
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)

Generated On: 26 Nov 2020 11:13:36

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5
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)

Generated On: 26 Nov 2020 11:13:36

SAEID	USA-US113-2020-MRNA-1273-P301000013
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5
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

Audit

US3752025 (Prod: Baptist Health Center for Clinical Research)

US3752025

Form: Participant Creation

Generated On: 26 Nov 2020 11:13:36

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:04:34

US3752025

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 15:54:29

US3752025

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Aug 2020 18:04:34

US3752025

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	10 Aug 2020 18:04:34

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 15:54:30

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Age](#)

Audit	User	Time (GMT)
User entered '58'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '58'	System	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:36

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:55:42

US3752025

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:36

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 18:04:48

US3752025

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 15:54:29

US3752025

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 18:04:51

US3752025

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:04:51

US3752025

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:13:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:56:54

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:57:22

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: Gastrooesophageal 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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2017'	System	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:57:49

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:36

Condition

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 1989'	System	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '1989'	System	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 1989'	System	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '1989'	System	11 Aug 2020 13:58:51

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	11 Aug 2020 14:01:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2019'	System	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:59:29

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:36

Condition

Audit	User	Time (GMT)
DataPoint Verified.	(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
User entered 'Back surgery'	(b) (4), (b) (6)	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:51:11
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 1989'	System	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '1989'	System	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 1989'	System	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '1989'	System	11 Aug 2020 14:00:31

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:36

Condition

Audit	User	Time (GMT)
DataPoint Verified.	(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
User entered 'Back surgery'	(b) (4), (b) (6)	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2019'	System	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2019'	System	11 Aug 2020 14:01:10

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	11 Aug 2020 14:03:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 1978'	System	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '1978'	System	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 1978'	System	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '1978'	System	11 Aug 2020 14:01:51

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
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 14:03:07
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2004'	System	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2004'	System	11 Aug 2020 14:02:24

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 15:37:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2017'	System	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '2017'	System	13 Nov 2020 15:35:20

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 15:57:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:22
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:41:12

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: 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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:56
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:42:30

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:56:23
User coded data point as SOC: Gastrointestinal disorders, HLGT: 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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:56:28
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:43:46

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:56:43
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Pollakiuria, LLT: Urinary frequency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:47:48
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 15:47:48
Data point term sent to Coder	System	13 Nov 2020 15:46:24
User entered 'Urinary Frequency'	(b) (4), (b) (6)	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:45:31

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:57:07
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:06:59

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
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)	13 Nov 2020 16:23:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 16:23:49
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:58:48
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:07:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 16:09:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:59:20
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:08:42

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:00:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:00:20
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:09:16

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 16:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:42:33
User opened query 'Source says start date = unk unk 1989' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:02:53
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System). DataPoint Un-verified.	System (b) (4), (b) (6)	17 Nov 2020 22:42:48 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). DataPoint Verified.	System (b) (4), (b) (6)	17 Nov 2020 22:42:33 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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:02:15
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:10:44

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:03:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:34:17

US3752025

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
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)	19 Nov 2020 18:42:01
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 18:42:01
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) (b) (4)	13 Nov 2020 16:36:09
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 16:36:09
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 16:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:35:37

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:07:17
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:07:21
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:36:15

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 11:13:36

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:07:41
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 11:13:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:07:48
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:38:03

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:58'	(b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:58'	System	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '165.0' cm	(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: 26 Nov 2020 11:13:36

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '244.5' lb	(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: 26 Nov 2020 11:13:36

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(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: 26 Nov 2020 11:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:13:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 14:03:55

US3752025

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:36

Was the physical examination performed?

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:13:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:36

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:36

If No, what is the reason?

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:13:36

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'un UNK 1989'	(b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:36

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:13:36

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:05:23

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

[Specify](#)

Audit	User	Time (GMT)
User entered 'Disabled'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

Other

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:36

[Specify](#)

Audit	User	Time (GMT)
User entered 'Resides in duplex apartment'	(b) (4), (b) (6)	11 Aug 2020 14:06:32

US3752025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:06:46

US3752025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:06:46

US3752025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 14:06:46

US3752025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Aug 2020 14:06:46

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:36

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 16:59:12

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:36

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	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) [REDACTED]	10 Aug 2020 16:59:12

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:36

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	11 Aug 2020 14:08:39
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) [REDACTED]	10 Aug 2020 16:59:12

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:36

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:07:03

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:36

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:07:03

US3752025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:36

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:13:36

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(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: 26 Nov 2020 11:13:36

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:07:03

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:36

Height

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:13:36

[Weight](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Height

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:13:36

[Weight](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:58'	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	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: 26 Nov 2020 11:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:45
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:13:36

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:45
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:45
Query 'Data is required. Please provide.' answered by System data change (Site from 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

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:10:45
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Height

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:13:36

[Weight](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:36

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:13:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	(b) (4), (b) (6)	11 Aug 2020 14:10:14

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	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: 26 Nov 2020 11:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:11:33
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:13:36

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:11:33
Query 'Data is required. Please provide.' answered by System data change (Site from 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

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:11:33
Query 'Data is required. Please provide.' answered by System data change (Site from 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

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 14:11:33
Query 'Data is required. Please provide.' answered by System data change (Site from 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

US3752025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was the physical examination performed?

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:13:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(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: 26 Nov 2020 11:13:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:27'	(b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:27'	System	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 18:05:20

US3752025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:24:21

US3752025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:24:21

US3752025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:04'	(b) (4), (b) (6)	11 Aug 2020 14:24:21

US3752025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:36

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:36

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '11:07'	(b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:36

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 14:24:40

US3752025

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:34:58

US3752025

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 14:34:58

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	11 Aug 2020 17:35:35
User entered '97.7'	System	11 Aug 2020 17:35:35

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	14 Aug 2020 18:11:14
User entered '98.2'	System	14 Aug 2020 18:11:14

US3752025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **PAIN AT INJECTION SITE.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **PAIN AT INJECTION SITE.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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' User entered 'None (0)'	System	12 Aug 2020 17:16:50
	System	12 Aug 2020 17:16:50

US3752025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 00:12:14

US3752025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 00:12:14

US3752025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Aug 2020 00:12:14

US3752025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 00:12:14

US3752025

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:21:14

US3752025

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:21:14

US3752025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:29:49

US3752025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 18:29:49

US3752025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Aug 2020 18:29:49

US3752025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:29:49

US3752025

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:23:34

US3752025

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 15:23:34

US3752025

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:23:46

US3752025

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 15:23:46

US3752025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:24:01

US3752025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 15:24:01

US3752025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	21 Sep 2020 15:24:01

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:21'	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:23:01
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:23:01
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:13:36

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:23:01
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:23:01
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:23:01
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 20:22:31

US3752025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:36

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:13:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(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: 26 Nov 2020 11:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:13:36

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 20:23:59

US3752025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 20:23:59

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:19'	(b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:36

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 15:24:41

US3752025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 20:24:32

US3752025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 20:24:32

US3752025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:42'	(b) (4), (b) (6)	21 Sep 2020 20:24:32

US3752025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(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: 26 Nov 2020 11:13:36

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:13:36

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '09:39'	(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: 26 Nov 2020 11:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:13:36

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 20:24:44

US3752025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 20:24:49

US3752025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 20:24:49

US3752025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: '75fccdf-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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **PAIN AT INJECTION SITE.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: '37796460-5dcb-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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: '00bff71a-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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: '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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: '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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: '00bff71a-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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:24:41

US3752025

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:24:28

US3752025

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 12:24:28

US3752025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:24:45

US3752025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 12:24:45

US3752025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Oct 2020 12:24:45

US3752025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 12:24:45

US3752025

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:36

US3752025

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 18:47:36

US3752025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:45

US3752025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:45

US3752025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:45

US3752025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:45

US3752025

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:47:48

US3752025

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 18:47:48

US3752025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:01:44

US3752025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Oct 2020 16:01:44

US3752025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	19 Oct 2020 16:01:44

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	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: 26 Nov 2020 11:13:36

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:10'	(b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '97.3' F	(b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '99'	(b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '122'	(b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '82'	(b) (4), (b) (6)	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 16:02:25

US3752025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:02:35

US3752025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:36

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	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: 26 Nov 2020 11:13:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:02:54

US3752025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 16:08:03
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from 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: 26 Nov 2020 11:13:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:15'	(b) (4), (b) (6)	19 Oct 2020 16:02:54

US3752025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:02:58

US3752025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:02:58

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

[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 Oct 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: 26 Nov 2020 11:13:36

[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 Oct 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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

[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 Oct 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: 26 Nov 2020 11:13:36

[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 Oct 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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

[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 Oct 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: 26 Nov 2020 11:13:36

[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 Oct 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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

[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 Oct 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: 26 Nov 2020 11:13:36

[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 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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

[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 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: 26 Nov 2020 11:13:36

[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 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: 26 Nov 2020 11:13:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:11:07
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:11:07

US3752025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:13:36

[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 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: 26 Nov 2020 11:13:36

[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 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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:19:39

US3752025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 18:19:39

US3752025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Nov 2020 18:19:39

US3752025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:19:39

US3752025

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:19:43

US3752025

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 18:19:43

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:13:36

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 18:52:56

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
User closed query 'Correct temp to 97.9--delete leading 0.' (Site from CRA).	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:11:39
User entered 'None (None)'	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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:11:43
User entered 'None (None)'	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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:11:50
User entered 'None (None)'	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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:11:52
User entered 'None (None)'	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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:11:55
User entered 'None (None)'	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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:11:58
User entered 'None (None)'	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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:12:03
User entered 'None (None)'	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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:12:04
User entered 'None (None)'	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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:12:06
User entered 'None (None)'	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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:12:08
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:52:56
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 18:53:39

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:13:46
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:53:39
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:13:49
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:53:39
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:13:53
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:53:39
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:13:54
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:53:39
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:13:59
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:53:39
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:14:01
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:53:39
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:14:06
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:53:39
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:14:08
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:53:39
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:14:09
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:53:39
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:14:15
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:53:39
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 18:56:35

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:35
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:56:35
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:38
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:56:35
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:30:35
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:56:35
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:30:36
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:56:35
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:30:44
User entered 'None (None)'	Amanda Horn (b) (4)	12 Oct 2020 18:56:35
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:36

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Nov 2020 15:26:38

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	17 Nov 2020 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:31:11
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 15:27:03

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	17 Nov 2020 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:33:32
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 15:27:16

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:35:44
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 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:35:45
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 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:35:47
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 15:29:41

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	17 Nov 2020 15:29:56

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:39:10
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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	17 Nov 2020 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:40:40
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 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:42:06
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 15:30:12

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	17 Nov 2020 15:30:32

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:45:08
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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	17 Nov 2020 15:31:00

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:46:09
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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	17 Nov 2020 15:31:48

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:27:38
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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	17 Nov 2020 15:32:04

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:57:50
User entered '93' 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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:58:49
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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 21:25:10

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:59:49
User entered 'None (None)'	Amanda Horn (b) (4)	19 Nov 2020 21:25:10
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:00:32
User entered 'None (None)'	Amanda Horn (b) (4)	19 Nov 2020 21:25:10
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 22:58:54

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:01:34
User entered 'None (None)'	Amanda Horn (b) (4)	19 Nov 2020 22:58:54
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 23:06:49

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:53
User entered 'None (None)'	Amanda Horn (b) (4)	20 Nov 2020 23:06:49
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:54
User entered 'None (None)'	Amanda Horn (b) (4)	20 Nov 2020 23:06:49
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:55
User entered 'None (None)'	Amanda Horn (b) (4)	20 Nov 2020 23:06:49
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:57
User entered 'None (None)'	Amanda Horn (b) (4)	20 Nov 2020 23:06:49
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:59
User entered 'None (None)'	Amanda Horn (b) (4)	20 Nov 2020 23:06:49
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Nov 2020 19:55:40

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:10:53
User entered 'None (None)'	Amanda Horn (b) (4)	22 Nov 2020 19:55:40
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:14:34
User entered 'None (None)'	Amanda Horn (b) (4)	22 Nov 2020 19:55:40
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:14:38
User entered 'None (None)'	Amanda Horn (b) (4)	22 Nov 2020 19:55:40
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:14:40
User entered 'None (None)'	Amanda Horn (b) (4)	22 Nov 2020 19:55:40
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:09
User entered '94' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:22
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:27
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:38
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:42
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:53
User entered 'Moderate (Moderate)' 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)	23 Nov 2020 18:53:33
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:56
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:15:59
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:16:00
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:16:02
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:33

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:16:26
User entered '95' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:16:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:16:54
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:16:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:17:10
User entered 'Moderate (Moderate)' 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)	23 Nov 2020 18:53:43
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:17:11
User entered 'Moderate (Moderate)' 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)	23 Nov 2020 18:53:43
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:17:13
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:17:15
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:17:18
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:33
User entered empty.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	Amanda Horn (b) (4)	23 Nov 2020 18:53:43

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:13:36

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	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: 26 Nov 2020 11:13:36

[Date](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 22:19:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:13:36

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Sore Throat](#)

Audit	User	Time (GMT)
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: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:36

[Date of Visit](#)

Audit	User	Time (GMT)
Query 'Per ETRTR: Date is still as 10Nov20. Please update to 09Nov20 if applicable, thanks.' canceled (Site from CRA).	(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	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)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:36

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:58:04
	(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)	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)	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:36

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:18:35
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)	
User closed query 'Source says date of covid test was 09NOV2020. Is this correct? If so, please update EDC' (Site from CRA).	Amanda Horn (b) (4)	23 Nov 2020 19:05:26
DataPoint Verified.	(b) (4)	
User entered '10 Nov 2020' reason for change: Data Entry Error	(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
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)	
User entered '10 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 19:51:38
	Amanda Horn (b) (4)	12 Nov 2020 22:25:20
	(b) (4)	

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:36

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 22:25:20

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
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)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:42:49
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: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:45:47
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: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:52:03
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: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:52:09
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: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
User closed query 'Please reconcile and enter start date and stop date of hypotension meeting criteria in previous question' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:21:33
Query 'Please reconcile and enter start date and stop date of hypotension meeting criteria in previous question' answered with 'updated' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:53:56
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). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 04:56:36
User entered empty.	Amanda Horn (b) (4)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	12 Nov 2020 22:31:15

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:36

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:58:09
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 (3)

Generated On: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:58:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:50:57

US3752025

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:01:05
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 (5)

Generated On: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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)	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)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	19 Nov 2020 21:25:49
User entered empty.	Amanda Horn (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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)	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)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 18:56:53
User entered empty.	Amanda Horn (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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 (6)

Generated On: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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 (7)

Generated On: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	16 Nov 2020 19:08:13

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
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)	
	Amanda Horn (b) (4)	17 Nov 2020 14:31:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 18:49:29
User entered 'Yes (Y)'	Amanda Horn (b) (4)	12 Oct 2020 18:49:19
	(b) (4)	

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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	Amanda Horn (b) (4)	17 Nov 2020 14:31:35
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

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	12 Oct 2020 18:49:19

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 18:50:16

US3752025

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	12 Oct 2020 18:50:39
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	12 Oct 2020 18:50:28
	(b) (4)	

US3752025

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:13:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:22:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (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: 26 Nov 2020 11:13:36

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:57:13
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. ' answered with 'SUBJECT WAS SEEN FOR ILLNESS VISIT 09OCT2020 AND ASSESSED FOR COVID-19' (Site from DM).	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 17:04:08
User opened query 'Per MM, please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 15:54:32
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (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.	Coder Import (b) (4) (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) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:23:00
User entered '2 Oct 2020'	Amanda Horn (b) (4)	12 Oct 2020 18:58:52
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:23:03
User entered 'No (N)'	Amanda Horn (b) (4)	12 Oct 2020 18:58:52
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:36

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:23:51
User entered 'None (NONE)'	Amanda Horn (b) (4)	12 Oct 2020 18:58:52
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:23:54
User entered '1'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 18:58:52

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:36

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:57:17
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. ' answered with 'SUBJECT WAS SEEN 08OCT2020 FOR ILLNESS VISIT. COVID PCR WAS NEGATIVE' (Site from DM).	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 17:04:52
User opened query 'Per MM, please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 15:54:48
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, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\23.0.	Coder Import (b) (4) (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) (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.' answered with 'UPDATED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	02 Nov 2020 15:11:44
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	02 Nov 2020 15:11:37
User entered 'NON-CARDIAC CHEST TIGHTNESS' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	02 Nov 2020 15:11:37

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:36

[Adverse event](#)

Audit	User	Time (GMT)
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), (b) (6)	02 Nov 2020 14:28:30
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.	Coder Import (b) (4)	12 Oct 2020 19:01:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Oct 2020 19:01:23
Data point term sent to Coder	System	12 Oct 2020 19:00:08
User entered 'CHEST TIGHTNESS'	Amanda Horn (b) (4)	12 Oct 2020 18:59:25
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:25:26
User entered 'No (N)'	Amanda Horn (b) (4)	12 Oct 2020 18:59:25
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:36

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:26:04
User entered 'None (NONE)'	Amanda Horn (b) (4)	12 Oct 2020 18:59:25
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:26:07
User entered '1'	Amanda Horn (b) (4) (b) (4)	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:13:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 18:59:25

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:26:28
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: 26 Nov 2020 11:13:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
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

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:26:43
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	13 Nov 2020 21:01:13
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:26:58
User entered '0'	Haylee Rowe (b) (4)	12 Nov 2020 21:06:51
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:27:00
User entered '0'	Haylee Rowe (b) (4)	12 Nov 2020 21:06:51
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:57:27
	(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)	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 '1'	Haylee Rowe (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 20:55:04
User entered empty.	Haylee Rowe (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:27:37
User entered 'Not Applicable (NOT APPLICABLE)'	Haylee Rowe (b) (4)	12 Nov 2020 21:06:51
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:27:42
User entered '1'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:27:44
User entered '0'	Haylee Rowe (b) (4)	12 Nov 2020 21:06:51
	(b) (4)	

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[Outcome](#)

Audit	User	Time (GMT)
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)	13 Nov 2020 21:00:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Haylee Rowe (b) (4)	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Narrative](#)

Audit	User	Time (GMT)
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
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).	(b) (4), (b) (6)	19 Nov 2020 17:24:31
DataPoint Un-verified.	(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).	(b) (4), (b) (6)	19 Nov 2020 13:31:32
DataPoint Verified.	(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

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 21:06:51

US3752025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	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

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	23 Nov 2020 14:53:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:53:53
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. ' (Site from System).	System	23 Nov 2020 14:53:04
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 14:53:04
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. ' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:24:21
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) (b) (4)	12 Nov 2020 22:08:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 22:08:35
Data point term sent to Coder	System	12 Nov 2020 22:08:11

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'SYMPTOMATIC COVID-19'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:09:37
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: 26 Nov 2020 11:13:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:40:29
User closed query 'Source says Grade 4. Update edc or clarify.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:40:25
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
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:05:15
User opened query 'Source says Grade 4. Update edc or clarify.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:10:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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 '1'	Amanda Horn (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:11:45
User entered '1'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:11:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 22:07:17

US3752025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:13:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 22:07:17

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:13:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please remove Dose Unit in Dose per Administration field.' (Site from DM).	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
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) (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

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Source states this med continues. Please update EDC or clarify.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:18:46
	(b) (4), (b) (6)	19 Nov 2020 15:18:44
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (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). DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:30:49
	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:22:14
User entered '2 Sep 2020' reason for change: New Information	Amanda Horn (b) (4)	17 Nov 2020 14:58:36
User entered empty; reason for change New Information	(b) (4)	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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:34:42
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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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) (b) (4)	19 Oct 2020 16:06:44
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	19 Oct 2020 16:05:46 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) (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) (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
Query 'For coding purposes, references indicate different formulations for PROTONIX.	(b) (4), (b) (6)	26 Aug 2020 14:41:13

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
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).		
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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	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' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:04:52
User entered 'ABDOMINAL ISSUES'	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:38:48
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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:39:41
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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:40:00
User entered '1'	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
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) (b) (4)	25 Oct 2020 08:22:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:22:20
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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
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
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	17 Nov 2020 14:59:58
DataPoint Verified.	(b) (4)	
	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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
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
User entered 'UN Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 14:59:58
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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:26:23
User entered 'VARIES' reason for change: Data Entry Error	Amanda Horn (b) (4)	17 Nov 2020 15:01:52
User entered '12' reason for change: Data Entry Error	Haylee Rowe (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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:26:28
User entered 'UNITS' reason for change: Data Entry Error	Amanda Horn (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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:26:32
User entered 'other (OTHER)' reason for change:	Amanda Horn (b) (4)	17 Nov 2020 15:01:52
Data Entry Error	(b) (4)	
User entered 'twice daily (BID)' reason for change:	Haylee Rowe (b) (4)	12 Nov 2020 20:22:21
Data Entry Error	(b) (4)	
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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	17 Nov 2020 15:01:52
User entered empty; reason for change Data Entry Error	Haylee Rowe (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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	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)	17 Nov 2020 15:05:46

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:31:02
User entered '1'	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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:31:44
User entered '1'	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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:32:11
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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
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)	17 Nov 2020 15:08:17
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:32:21
User entered 'UNITS'	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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:32:50
User entered '1'	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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Interval Dosage Unit 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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	17 Nov 2020 15:10:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(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)	17 Nov 2020 15:09:04
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:55
User entered '1'	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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	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)	17 Nov 2020 15:16:14

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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)	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)	17 Nov 2020 15:16:56

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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-STEROIDS, 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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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-STEROIDS, 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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	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)	17 Nov 2020 15:20:11
	(b) (4)	

US3752025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:50:47
User entered 'COVID-19'	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: 26 Nov 2020 11:13:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[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: 26 Nov 2020 11:13:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 15:20:47

US3752025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:13:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Source says start date was 10NOV2020' (Site from CRA).	(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: 26 Nov 2020 11:13:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 13:38:14
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: 26 Nov 2020 11:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 13:38:14
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: 26 Nov 2020 11:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:22:08
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: 26 Nov 2020 11:13:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 13:38:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:22:10
User entered '1'	(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: 26 Nov 2020 11:13:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 13:38:14
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: 26 Nov 2020 11:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:05:56
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: 26 Nov 2020 11:13:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 13:38:14
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:06:01
User entered '1'	(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: 26 Nov 2020 11:13:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 13:38:14
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: 26 Nov 2020 11:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:20:30
User entered '1'	(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: 26 Nov 2020 11:13:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 13:38:14
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: 26 Nov 2020 11:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:01:53
User entered '1'	(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: 26 Nov 2020 11:13:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:13:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 13:38:14
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: 26 Nov 2020 11:13:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:13:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 14:31'	System	24 Nov 2020 14:31:18

US3752025

Folder: SAE USA-US113-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:13:36

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 entered '1'	(b) (4), (b) (6)	24 Nov 2020 14:31:18