

US3552103 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:51:43

All time stamps listed in this document are displayed in GMT

US3552103

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

[Participant ID](#)

US3552103

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

US3552103

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 17:47:57

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Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 17:47:57

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 17:47:57

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Condition	CERVICAL DISCS REPLACED
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	MAY 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN AUG 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2008
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2008
Start Year (derived)	2008
Stop Month and Year (derived)	AUG 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN DEC 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 1994
Stop date completely unknown	False
Start Month and Year (derived)	DEC 1994
Start Year (derived)	1994
Stop Month and Year (derived)	DEC 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Condition	ALLERGY TO MORPHINE
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Condition	ANXIETY WITH HEIGHTS
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Condition	BILE REFLUX
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Condition	ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	11:34 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:34
Height (xxx.x)	65 in
Weight (xxx.x)	207.2 lb
BMI (xxx.x)	34.55198 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 21 Feb 2021 17:47:57

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Date of assessment (dd MMM yyyy) 20 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN AUG 2008

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

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

GROCERY SHOPPING, HAIR SALON, LIVES WITH FAMILY THAT TRAVELED, SEES GRANDCHILDREN 1X / WEEK.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

PRODUCTION RELEASE (v12.003 EAB) (1725)

23 of 1925

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Folder: Screening

Form: Risk of Exposure

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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
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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 106494

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	11:34 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:34
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 13:15
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 12:45

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	12:15 (24 HR)
Collection date and time (derived)	20 AUG 2020 12:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:20	20 AUG 2020 12:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 13:16

PC Open Date & Time

20 AUG 2020 13:05

PC Close Date & Time

20 AUG 2020 15:35

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

97.1 °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	20 AUG 2020 21:10
PC Open Date & Time	20 AUG 2020 16:30
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

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

96.1 °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

21 AUG 2020 12:46

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 14:50

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

96.6 °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

23 AUG 2020 12:41

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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

24 AUG 2020 13:42

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

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

96.6 °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 AUG 2020 16:33

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

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

97.1 °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

26 AUG 2020 15:19

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

20 AUG 2020 13:17

PC Open Date & Time

20 AUG 2020 13:05

PC Close Date & Time

20 AUG 2020 15:35

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

20 AUG 2020 21:11

PC Open Date & Time

20 AUG 2020 16:30

PC Close Date & Time

21 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

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

21 AUG 2020 12:39

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

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

22 AUG 2020 14:50

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

23 AUG 2020 12:42

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 13:42

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 16:33

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

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

26 AUG 2020 15:19

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 13:17
PC Open Date & Time	20 AUG 2020 13:05
PC Close Date & Time	20 AUG 2020 15:35

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 21:12
PC Open Date & Time	20 AUG 2020 16:30
PC Close Date & Time	21 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 1925

EAB) (1725)

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:40
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 1925

EAB) (1725)

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 14:51
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:42
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 13:43
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 16:33
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 15:20
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3552103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:47:58

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:47:58

Generated On: 11 Aug 2021 22:51:43

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 16:05
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:47:58

Generated On: 11 Aug 2021 22:51:43

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3552103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:47:58

Generated On: 11 Aug 2021 22:51:43

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.

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

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

WORSENING DEPRESSION

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

Which arm was used to give treatment? Left Arm ☐
Right Arm ☐

What was the frequency of the study treatment dosing? _____

What was the route of administration for the study treatment? _____

US3552103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:47:58

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

16:50 (24 HR)

Collection date and time (derived)

21 SEP 2020 16:50

US3552103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:55	21 SEP 2020 16:55
Nasopharyngeal Swab 2	No		

US3552103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:47:58

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:47:58

Generated On: 11 Aug 2021 22:51:43

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3552103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:47:58

Generated On: 11 Aug 2021 22:51:43

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.

US3552103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:47:58

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

10:28 (24 HR)

Collection date and time (derived)

23 OCT 2020 10:28

US3552103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:58

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 OCT 2020 10:40:32
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 00:06:23

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 NOV 2020 04:48:59
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 00:06:12

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 18:34:48
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 01:01:13

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 21:15:20

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 10:42:50

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Date and time of submission

21 DEC 2020 10:55:28

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 DEC 2020 04:10:55
Patient Cloud Open Date & Time	26 DEC 2020 00:01
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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 00:06:24

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 23:07:52

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 18:29:56

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 23:30:59

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 17:04:41

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 12:25:50

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 08:11:08
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 12:40:27

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 05:06:10
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 15:18:42

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 06:17:05

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 13:27:59

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 15:07:16

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 19:13:58
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 00:03:13
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 16:34:37

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 12:00:27

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Date and time of submission

01 MAY 2021 00:21:31

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 MAR 2022 00:01
Patient Cloud Close Date & Time	23 MAR 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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15 JUN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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29 JUN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Date and time of submission

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02 JUL 2022 00:01

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06 JUL 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

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23 JUL 2022 00:01

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27 JUL 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

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30 JUL 2022 00:01

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03 AUG 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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06 AUG 2022 00:01

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10 AUG 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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13 AUG 2022 00:01

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17 AUG 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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 ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3552103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:51:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 05:05:55

US3552103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:57

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:19:32

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:19:32

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 15:24:47

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:11:30

Generated On: 11 Aug 2021 22:51:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	14:03 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 14:03
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552103

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:11:30

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3552103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 15:24:47

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	14:16 (24 HR)
Collection date and time (derived)	22 MAR 2021 14:16

US3552103

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:24:47

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552103

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:51:43

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

US3552103

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:51:43

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552103

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

Form: Visit Date

Data signed: (b) (4) 27 Feb 2021 17:53:50

Generated On: 11 Aug 2021 22:51:43

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

Visit date (dd MMM yyyy)	12 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3552103

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:24:47

Generated On: 11 Aug 2021 22:51:43

Date of updated informed consent (dd MMM yyyy)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3552103

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 27 Feb 2021 17:53:50

Generated On: 11 Aug 2021 22:51:43

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3552103

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 27 Feb 2021 17:53:50

Generated On: 11 Aug 2021 22:51:43

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	15:25 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 15:25
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3552103

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 27 Feb 2021 17:53:50

Generated On: 11 Aug 2021 22:51:43

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 16:15
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 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)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3552103

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

Form: Physical Examination

Data signed: (b) (4) 27 Feb 2021 17:53:50

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3552103

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

Form: Exposure

Data signed: (b) (4) 27 Feb 2021 17:53:50

Generated On: 11 Aug 2021 22:51:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 15:45 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 15:45

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

US3552103

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	13:40 (24 HR)
Collection date and time (derived)	12 JAN 2021 13:40

US3552103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	13:45
Collection Date and Time (derived)	12 JAN 2021 13:45

US3552103

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

Form: Continuing

Data signed: (b) (4) 27 Feb 2021 17:53:50

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 16:53:44

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 16:53:43

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3552103

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 15:24:47

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Mar 2021 15:24:47

Generated On: 11 Aug 2021 22:51:43

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	14:03 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 14:03
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Mar 2021 15:24:47

Generated On: 11 Aug 2021 22:51:43

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	15:29 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 15:29
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3552103

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 15:24:47

Generated On: 11 Aug 2021 22:51:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3552103

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Mar 2021 15:24:47

Generated On: 11 Aug 2021 22:51:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 MAR 2021

What was the treatment time? (00:00-23:59) 14:59 (24 HR)

Treatment Date and Time (derived) 22 MAR 2021 14:59

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

US3552103

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:24:47

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 16:21:13

Generated On: 11 Aug 2021 22:51:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 16:21:07

Generated On: 11 Aug 2021 22:51:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3552103

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3552103

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

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.

US3552103

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 APR 2021

Collection time (00:00-23:59)

14:16 (24 HR)

Collection date and time (derived)

16 APR 2021 14:16

US3552103

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 03:19:32

Generated On: 11 Aug 2021 22:51:43

AEID	
Adverse event	WORSENING DEPRESSION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	03 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 03:19:32

Generated On: 11 Aug 2021 22:51:43

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3552103

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 03:19:32

Generated On: 11 Aug 2021 22:51:43

AEID	
Adverse event	RIGHT MYODESOPSIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 03:19:32

Generated On: 11 Aug 2021 22:51:43

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

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

Yes ☒

No ☐

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

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 450

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication DICYCLOMINE

Prophylaxis Yes ☐
No ☒

Indication IRRITABLE BOWEL SYNDROME

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 19:38:52

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Name of Medication LORAZEPAM

Prophylaxis Yes ☒
No ☐

Indication ANXIETY WITH HEIGHTS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 19:38:52

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHES AND
DEGENERATIVE DISC DISEASE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 19:38:52

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 19:38:52

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Name of Medication VITAMIN B

Prophylaxis Yes ☒
No ☐

Indication HEALTH PROMOTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

3 TIMES PER WEEK

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 19:38:52

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1-2

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Apr 2021 19:38:52

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Name of Medication NASACORT

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 55

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Apr 2021 19:38:52

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Apr 2021 19:38:52

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Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 19:38:52

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Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication BILE REFLUX

Dose per administration 20

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 19:38:52

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Name of Medication LEVOTHYROIXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

Name of Medication ADDERALL

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 19:38:52

Generated On: 11 Aug 2021 22:51:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3552103

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 17:47:40

Generated On: 11 Aug 2021 22:51:43

Date of dosing discontinuation (dd MMM yyyy)	21 SEP 2020
--	-------------

Primary reason for dosing discontinuation	AE (specify) <input checked="" type="radio"/>
	SAE (specify) <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-up <input type="radio"/>
	Physician decision (specify) <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol deviation (specify) <input type="radio"/>
	Study Terminated By Sponsor <input type="radio"/>
	Withdrawal of consent by participant (specify) <input type="radio"/>
	Due to SARS-COV-2 <input type="radio"/>
	Other <input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #1
---	-------

US3552103

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:51:43

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 ☐

Audit

US3552103 (Prod: Saint Louis University)

US3552103

Form: Participant Creation

Generated On: 11 Aug 2021 22:51:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'US3552103'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:44:43

US3552103

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:04:52

US3552103

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:44:44

US3552103

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:04:52

US3552103

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'SCRN'	System	20 Aug 2020 20:04:52

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered (b) (6) 1969'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:44:45

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '51'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'YEARS'	System	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '51'	System	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 20:05:20
User entered 'Female (F)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	20 Aug 2020 20:05:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Aug 2020 20:05:15
	Mikayla Frye (b) (4)	20 Aug 2020 20:05:15
	(b) (4)	

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '20 Aug 2020'	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Aug 2020'	System	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2020'	System	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Amendment 2 (2)'	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:44:44

US3552103

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'l'	System	20 Aug 2020 17:34:01

US3552103

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:34:01

US3552103

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:51:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:39

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:07:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:07:27
Data point term sent to Coder	System	20 Aug 2020 20:06:28
User entered 'Depression'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Un UNK 2001'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Jan 2001'	System	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2001'	System	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
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.	(b) (4) Coder Import (b) (4)	20 Aug 2020 20:07:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:07:28
Data point term sent to Coder	System	20 Aug 2020 20:06:28
User entered 'Irritable bowel syndrome'	Mikayla Frye (b) (4)	20 Aug 2020 20:06:17
	(b) (4)	

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'UN UNK 2018'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Jan 2018'	System	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2018'	System	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:08:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:08:29
Data point term sent to Coder	System	20 Aug 2020 20:07:30
User entered 'Seasonal allergies'	Mikayla Frye (b) (4)	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'UN UNK 2012' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	02 Oct 2020 18:02:52
User entered 'un UNK 2016'	(b) (4)	
	Mikayla Frye (b) (4)	20 Aug 2020 20:06:45
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:45

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Jan 2012'	System	02 Oct 2020 18:02:52
User entered 'Jan 2016'	System	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2012'	System	02 Oct 2020 18:02:52
User entered '2016'	System	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 20:08:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 20:08:29
Data point term sent to Coder	System	20 Aug 2020 20:07:30
User entered 'Headaches'	Mikayla Frye (b) (4)	20 Aug 2020 20:07:02

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'un UNK 1980'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:02

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:02

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Jan 1980'	System	20 Aug 2020 20:07:02

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '1980'	System	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	20 Aug 2020 20:07:02

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	20 Aug 2020 20:07:02

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
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)	05 Oct 2020 09:47:02
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 'data pending' (Site from DM).	Cassandra Zehenny (b) (4)	29 Sep 2020 18:31:02
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)	25 Sep 2020 12:03:55
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: Intervertebral disc operation, LLT: Intervertebral disc operation - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 21:18:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 21:18:40
Data point term sent to Coder	System	20 Aug 2020 20:08:32
User entered 'Cervical discs replaced'	Mikayla Frye (b) (4)	20 Aug 2020 20:07:38

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'un UNK 2018'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:38

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:38

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:38

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'un May 2019'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:38

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Jan 2018'	System	20 Aug 2020 20:07:38

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2018'	System	20 Aug 2020 20:07:38

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'May 2019'	System	20 Aug 2020 20:07:38

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2019'	System	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
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)	05 Oct 2020 09:47:17
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 'data pending' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	29 Sep 2020 18:32:30
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)	25 Sep 2020 12:04:06
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)	20 Aug 2020 20:09:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:09:31
Data point term sent to Coder	System	20 Aug 2020 20:08:33
User entered 'Hysterectomy'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'un Aug 2008'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'un Aug 2008'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Aug 2008'	System	20 Aug 2020 20:08:06

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2008'	System	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Aug 2008'	System	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2008'	System	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
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)	20 Aug 2020 20:10:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:10:20
Data point term sent to Coder	System	20 Aug 2020 20:09:34
User entered 'Tubal ligation'	Mikayla Frye (b) (4)	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'un Dec 1994'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	20 Aug 2020 20:09:47
User entered 'No (N)' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:47
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	20 Aug 2020 20:09:05
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:05

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Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'un Dec 1994'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:05

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Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Dec 1994'	System	20 Aug 2020 20:09:05

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Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '1994'	System	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Dec 1994'	System	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '1994'	System	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 20:10:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 20:10:20
Data point term sent to Coder	System	20 Aug 2020 20:09:34
User entered 'Allergy to morphine'	Mikayla Frye (b) (4)	20 Aug 2020 20:09:33
	(b) (4)	

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'un UNK 2003'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Jan 2003'	System	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2003'	System	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 17:48:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 17:48:50
Data point term sent to Coder	System	30 Sep 2020 16:19:13
User entered 'anxiety with heights'	Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'un UNK 2017'	(b) (4) Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Jan 2017'	System	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2017'	System	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Bile reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 05:28:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 05:28:29
Data point term sent to Coder	System	12 Oct 2020 17:55:06
User entered 'bile reflux'	Stanley Doublin (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'un UNK 2017'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Jan 2017'	System	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2017'	System	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:51:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\23.0.	Coder Import (b) (4)	19 Jan 2021 22:37:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Jan 2021 22:37:10
Data point term sent to Coder	System	19 Jan 2021 22:35:56
User entered 'degenerative disc disease'	Cassandra Zehenny (b) (4)	19 Jan 2021 22:35:33

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Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 22:35:33

US3552103

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 22:35:33

US3552103

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 22:35:33

US3552103

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 22:35:33

US3552103

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 22:35:33

US3552103

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	19 Jan 2021 22:35:33

US3552103

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	19 Jan 2021 22:35:33

US3552103

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	19 Jan 2021 22:35:33

US3552103

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	19 Jan 2021 22:35:33

US3552103

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:51:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	19 Jan 2021 22:37:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Jan 2021 22:37:10
Data point term sent to Coder	System	19 Jan 2021 22:35:56
User entered 'hypothyroidism'	Cassandra Zehenny (b) (4)	19 Jan 2021 22:35:47

US3552103

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 22:35:47

US3552103

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 22:35:47

US3552103

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 22:35:47

US3552103

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 22:35:47

US3552103

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 22:35:47

US3552103

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	19 Jan 2021 22:35:47

US3552103

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	19 Jan 2021 22:35:47

US3552103

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	19 Jan 2021 22:35:47

US3552103

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	19 Jan 2021 22:35:47

US3552103

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:51:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	20 Apr 2021 19:38:52
User coded data point as SOC: Psychiatric disorders, HLT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 13:20:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 13:20:48
Data point term sent to Coder	System	19 Apr 2021 13:19:37
User entered 'Attention deficit hyperactivity disorder'	Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:19:36

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Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'un UNK 2006'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Apr 2021 13:19:36

US3552103

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Apr 2021 13:19:36

US3552103

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:51:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Apr 2021 13:19:36

US3552103

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Apr 2021 13:19:36

US3552103

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:51:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Apr 2021 13:19:36

US3552103

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'Jan 2006'	System	19 Apr 2021 13:19:36

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Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '2006'	System	19 Apr 2021 13:19:36

US3552103

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	19 Apr 2021 13:19:36

US3552103

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	19 Apr 2021 13:19:36

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '20 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '11:34'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '20 Aug 2020 11:34'	System	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '65' in	(b) (4) Mikayla Frye (b) (4)	20 Aug 2020 20:14:51
DataPoint set to visible.	(b) (4) System	20 Aug 2020 17:34:01

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '207.2' lb	(b) (4) Mikayla Frye (b) (4)	20 Aug 2020 20:14:51
DataPoint set to visible.	(b) (4) System	20 Aug 2020 17:34:01

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
Amendment Manager: User entered '34.55198'	System	17 Sep 2020 00:16:19
User entered '34.6'	System	20 Aug 2020 20:14:51
DataPoint set to visible.	System	20 Aug 2020 17:34:01

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'kg/m2'	System	20 Aug 2020 20:14:51
DataPoint set to visible.	System	20 Aug 2020 17:34:01

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'nd' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 05:27:05
User opened query 'Data is required. Please provide.' (Site from System).	Mikayla Frye (b) (4)	20 Aug 2020 20:14:57
User entered empty.	(b) (4)	
	System	20 Aug 2020 20:14:51
	Mikayla Frye (b) (4)	20 Aug 2020 20:14:51
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'bpm'	System	20 Aug 2020 20:14:51

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'breaths/min'	System	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'mmHg'	System	20 Aug 2020 20:14:51

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'mmHg'	System	20 Aug 2020 20:14:51

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Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03

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Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:15:07

US3552103

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '20 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:15:07

US3552103

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '20 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

US3552103

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Surgically sterile (SURGICALLY STERILE)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

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Folder: Screening

Form: Childbearing Potential

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If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'UN Aug 2008' reason for change:	(b) (4)	
Data Entry Error	Mikayla Frye (b) (4)	20 Aug 2020 20:13:45
User entered 'un UNK 2007'	(b) (4)	
	Mikayla Frye (b) (4)	20 Aug 2020 20:10:26
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:43

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Grocery shopping, hair salon, lives with family that traveled, sees grandchildren 1x / week.'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:43

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:43

US3552103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '20 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:43

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:43

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'VISIT1'	System	20 Aug 2020 20:19:43

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 17:20:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:54:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:54:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 17:20:34
User entered '106494' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 17:20:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 17:20:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:55

US3552103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:43

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	21 Sep 2020 17:14:03
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:46:32

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User accepted default value 'Pre-Dose (PREDOSE)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '20 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '11:34'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered '20 Aug 2020 11:34'	System	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 08:43:21
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:55:01
answered with 'NCS' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:16:19
User entered '96.7' F	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '72'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'bpm'	System	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '16'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'breaths/min'	System	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '132'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'mmHg'	System	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '83'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'mmHg'	System	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User accepted default value 'Post-Dose (POSTDOSE)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '20 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:54:56
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'time is correct as entered.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:33
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).	System	20 Aug 2020 20:21:21
User entered '13:15'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered '20 Aug 2020 13:15'	System	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 08:44:52
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:55:06
answered with 'NCS' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:16:19
User entered '96.7' F	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '72'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'bpm'	System	20 Aug 2020 20:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '18'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'breaths/min'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '135'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'mmHg'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '85'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'mmHg'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:42

US3552103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:42

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '20 Aug 2020'	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '12:45'	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered '20 Aug 2020 12:45'	System	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Left Arm (LEFT ARM)'	Cassandra Zehenny (b) (4) (b) (4)	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'ONCE'	System	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:13

US3552103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '20 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:13

US3552103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '12:15'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:13

US3552103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered '20 Aug 2020 12:15'	System	20 Aug 2020 20:22:13

US3552103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '20 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3552103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3552103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3552103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '12:20'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3552103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered '20 Aug 2020 12:20'	System	20 Aug 2020 20:22:26

US3552103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3552103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3552103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3552103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	20 Aug 2020 20:22:26

US3552103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 19:41:04

US3552103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'l'	System	27 Aug 2020 19:41:04

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:16:19', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '3280976c-8ed5-452d-8087-8113452288e4'	System	20 Aug 2020 18:16:38
User entered 'Yes (Y)'	System	20 Aug 2020 18:16:38

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:16:25', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '3280976c-8ed5-452d-8087-8113452288e4' User entered '96.7'	System	20 Aug 2020 18:16:38
	System	20 Aug 2020 18:16:38

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:16:28', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '3280976c-8ed5-452d-8087-8113452288e4'	System	20 Aug 2020 18:16:38
User entered 'No (N)'	System	20 Aug 2020 18:16:38

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:16:34', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '3280976c-8ed5-452d-8087-8113452288e4'	System	20 Aug 2020 18:16:38
User entered '20 Aug 2020 13:16'	System	20 Aug 2020 18:16:38

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '20 Aug 2020 13:05'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '20 Aug 2020 15:35'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:10:33', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e9afc4d9-939a-47a0-83d4-fdee81b723e6'	System	21 Aug 2020 02:10:48
User entered 'Yes (Y)'	System	21 Aug 2020 02:10:48

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:10:38', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e9afc4d9-939a-47a0-83d4-fdee81b723e6' User entered '97.1'	System	21 Aug 2020 02:10:48
	System	21 Aug 2020 02:10:48

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:10:41', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e9afc4d9-939a-47a0-83d4-fdee81b723e6'	System	21 Aug 2020 02:10:48
User entered 'No (N)'	System	21 Aug 2020 02:10:48

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:10:46', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e9afc4d9-939a-47a0-83d4-fdee81b723e6'	System	21 Aug 2020 02:10:48
User entered '20 Aug 2020 21:10'	System	21 Aug 2020 02:10:48

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '20 Aug 2020 16:30'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 2'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:46:09', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '810e9bf5-a37e-4052-a159-cabde5b940e3' User entered 'Yes (Y)'	System	21 Aug 2020 17:46:25
	System	21 Aug 2020 17:46:25

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:46:14', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '810e9bf5-a37e-4052-a159-cabdc5b940e3' User entered '96.1'	System	21 Aug 2020 17:46:25
	System	21 Aug 2020 17:46:25

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:46:17', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '810e9bf5-a37e-4052-a159-cabde5b940e3'	System	21 Aug 2020 17:46:25
User entered 'No (N)'	System	21 Aug 2020 17:46:25

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:46:23', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '810e9bf5-a37e-4052-a159-cabde5b940e3' User entered '21 Aug 2020 12:46'	System	21 Aug 2020 17:46:25
	System	21 Aug 2020 17:46:25

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 3'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:14', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '567284b8-eda0-4aac-b6cd-ca709962eaae' User entered 'Yes (Y)'	System	22 Aug 2020 19:50:35
	System	22 Aug 2020 19:50:35

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:20', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '567284b8-eda0-4aac-b6cd-ca709962eaae' User entered '98.4'	System	22 Aug 2020 19:50:35
	System	22 Aug 2020 19:50:35

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:24', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '567284b8-eda0-4aac-b6cd-ca709962eaae'	System	22 Aug 2020 19:50:35
User entered 'No (N)'	System	22 Aug 2020 19:50:35

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '567284b8-eda0-4aac-b6cd-ca709962eaae' User entered '22 Aug 2020 14:50'	System	22 Aug 2020 19:50:35
	System	22 Aug 2020 19:50:35

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 4'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:41:43', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '1f9f0be4-05d1-47c1-aeaf-4240df988094'	System	23 Aug 2020 17:41:56
User entered 'Yes (Y)'	System	23 Aug 2020 17:41:56

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:41:48', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '1f9f0be4-05d1-47c1-aeaf-4240df988094' User entered '96.6'	System	23 Aug 2020 17:41:56
	System	23 Aug 2020 17:41:56

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:41:51', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '1f9f0be4-05d1-47c1-aeaf-4240df988094'	System	23 Aug 2020 17:41:56
User entered 'No (N)'	System	23 Aug 2020 17:41:56

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:41:55', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '1f9f0be4-05d1-47c1-aeaf-4240df988094'	System	23 Aug 2020 17:41:56
User entered '23 Aug 2020 12:41'	System	23 Aug 2020 17:41:56

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 5'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:42:23', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b423a58e-41c9-4e12-b46e-78fdecf26488' User entered 'Yes (Y)'	System	24 Aug 2020 18:42:41
	System	24 Aug 2020 18:42:41

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:42:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b423a58e-41c9-4e12-b46e-78fdecf26488' User entered '96.0'	System	24 Aug 2020 18:42:41
	System	24 Aug 2020 18:42:41

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:42:32', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b423a58e-41c9-4e12-b46e-78fdecf26488'	System	24 Aug 2020 18:42:41
User entered 'No (N)'	System	24 Aug 2020 18:42:41

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:42:37', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b423a58e-41c9-4e12-b46e-78fdecf26488' User entered '24 Aug 2020 13:42'	System	24 Aug 2020 18:42:41
	System	24 Aug 2020 18:42:41

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 6'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:32:52', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '5d3f627f-53c3-4a2a-9fee-4b5a46acc04a' User entered 'Yes (Y)'	System	25 Aug 2020 21:33:09
	System	25 Aug 2020 21:33:09

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:32:56', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '5d3f627f-53c3-4a2a-9fee-4b5a46acc04a' User entered '96.6'	System	25 Aug 2020 21:33:09
	System	25 Aug 2020 21:33:09

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:01', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '5d3f627f-53c3-4a2a-9fee-4b5a46acc04a'	System	25 Aug 2020 21:33:09
User entered 'No (N)'	System	25 Aug 2020 21:33:09

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:08', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '5d3f627f-53c3-4a2a-9fee-4b5a46acc04a' User entered '25 Aug 2020 16:33'	System	25 Aug 2020 21:33:09
	System	25 Aug 2020 21:33:09

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 7'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:11', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '39146fe2-08d0-42a8-b37f-03020440e501'	System	26 Aug 2020 20:19:27
User entered 'Yes (Y)'	System	26 Aug 2020 20:19:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:16', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '39146fe2-08d0-42a8-b37f-03020440e501' User entered '97.1'	System	26 Aug 2020 20:19:27
	System	26 Aug 2020 20:19:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:19', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '39146fe2-08d0-42a8-b37f-03020440e501'	System	26 Aug 2020 20:19:27
User entered 'No (N)'	System	26 Aug 2020 20:19:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:23', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '39146fe2-08d0-42a8-b37f-03020440e501'	System	26 Aug 2020 20:19:27
User entered '26 Aug 2020 15:19'	System	26 Aug 2020 20:19:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:16:57', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '2e7f4747-1dbd-4aac-af7c-c32164bdbade'	System	20 Aug 2020 18:17:18
User entered 'None (1)'	System	20 Aug 2020 18:17:18

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '2e7f4747-1dbd-4aac-af7c-c32164bdbade'	System	20 Aug 2020 18:17:18
User entered 'No (N)'	System	20 Aug 2020 18:17:18

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:03', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '2e7f4747-1dbd-4aac-af7c-c32164bdbade'	System	20 Aug 2020 18:17:18
User entered 'No (N)'	System	20 Aug 2020 18:17:18

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:07', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '2e7f4747-1dbd-4aac-af7c-c32164bdbade'	System	20 Aug 2020 18:17:18
User entered 'None (1)'	System	20 Aug 2020 18:17:18

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:12', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '2e7f4747-1dbd-4aac-af7c-c32164bdbade'	System	20 Aug 2020 18:17:18
User entered '20 Aug 2020 13:17'	System	20 Aug 2020 18:17:18

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '20 Aug 2020 13:05'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '20 Aug 2020 15:35'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:10:52', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '11265ad9-6e9a-445a-8cab-f92eace74377'	System	21 Aug 2020 02:11:42
User entered 'None (1)'	System	21 Aug 2020 02:11:42

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:11:03', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '11265ad9-6e9a-445a-8cab-f92eace74377'	System	21 Aug 2020 02:11:42
User entered 'No (N)'	System	21 Aug 2020 02:11:42

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:11:20', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '11265ad9-6e9a-445a-8cab-f92eace74377'	System	21 Aug 2020 02:11:42
User entered 'No (N)'	System	21 Aug 2020 02:11:42

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:11:31', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '11265ad9-6e9a-445a-8cab-f92eace74377'	System	21 Aug 2020 02:11:42
User entered 'None (1)'	System	21 Aug 2020 02:11:42

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:11:38', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '11265ad9-6e9a-445a-8cab-f92eace74377'	System	21 Aug 2020 02:11:42
User entered '20 Aug 2020 21:11'	System	21 Aug 2020 02:11:42

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '20 Aug 2020 16:30'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 2'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:39:04', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b4784333-fe98-41b9-ad82-8c59b5fc2b31'	System	21 Aug 2020 17:39:34
User entered 'None (1)'	System	21 Aug 2020 17:39:34

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:39:07', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b4784333-fe98-41b9-ad82-8c59b5fc2b31'	System	21 Aug 2020 17:39:34
User entered 'No (N)'	System	21 Aug 2020 17:39:34

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:39:09', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b4784333-fe98-41b9-ad82-8c59b5fc2b31'	System	21 Aug 2020 17:39:34
User entered 'No (N)'	System	21 Aug 2020 17:39:34

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:39:27', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b4784333-fe98-41b9-ad82-8c59b5fc2b31'	System	21 Aug 2020 17:39:34
User entered 'None (1)'	System	21 Aug 2020 17:39:34

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:39:32', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b4784333-fe98-41b9-ad82-8c59b5fc2b31' User entered '21 Aug 2020 12:39'	System	21 Aug 2020 17:39:34
	System	21 Aug 2020 17:39:34

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 3'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:33', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4e70a751-c9e7-46a9-ab52-e52214f5ce1e'	System	22 Aug 2020 19:50:52
User entered 'None (1)'	System	22 Aug 2020 19:50:52

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:35', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4e70a751-c9e7-46a9-ab52-e52214f5ce1e'	System	22 Aug 2020 19:50:52
User entered 'No (N)'	System	22 Aug 2020 19:50:52

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:42', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4e70a751-c9e7-46a9-ab52-e52214f5ce1e'	System	22 Aug 2020 19:50:52
User entered 'No (N)'	System	22 Aug 2020 19:50:52

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:44', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4e70a751-c9e7-46a9-ab52-e52214f5ce1e' User entered 'None (1)'	System	22 Aug 2020 19:50:52
	System	22 Aug 2020 19:50:52

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:49', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4e70a751-c9e7-46a9-ab52-e52214f5ce1e'	System	22 Aug 2020 19:50:52
User entered '22 Aug 2020 14:50'	System	22 Aug 2020 19:50:52

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 4'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:05', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd69a1eef-5e2b-49fa-b364-e8476dd20ae3'	System	23 Aug 2020 17:42:21
User entered 'None (1)'	System	23 Aug 2020 17:42:21

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:08', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd69a1eef-5e2b-49fa-b364-e8476dd20ae3'	System	23 Aug 2020 17:42:21
User entered 'No (N)'	System	23 Aug 2020 17:42:21

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:10', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd69a1eef-5e2b-49fa-b364-e8476dd20ae3'	System	23 Aug 2020 17:42:21
User entered 'No (N)'	System	23 Aug 2020 17:42:21

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:13', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd69a1eef-5e2b-49fa-b364-e8476dd20ae3'	System	23 Aug 2020 17:42:21
User entered 'None (1)'	System	23 Aug 2020 17:42:21

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:19', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd69a1eef-5e2b-49fa-b364-e8476dd20ae3'	System	23 Aug 2020 17:42:21
User entered '23 Aug 2020 12:42'	System	23 Aug 2020 17:42:21

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 5'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:42:43', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b57162de-36ee-4360-b547-81e6249b0703'	System	24 Aug 2020 18:42:58
User entered 'None (1)'	System	24 Aug 2020 18:42:58

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:42:46', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b57162de-36ee-4360-b547-81e6249b0703'	System	24 Aug 2020 18:42:58
User entered 'No (N)'	System	24 Aug 2020 18:42:58

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:42:50', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b57162de-36ee-4360-b547-81e6249b0703'	System	24 Aug 2020 18:42:58
User entered 'No (N)'	System	24 Aug 2020 18:42:58

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:42:53', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b57162de-36ee-4360-b547-81e6249b0703'	System	24 Aug 2020 18:42:58
User entered 'None (1)'	System	24 Aug 2020 18:42:58

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:42:55', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b57162de-36ee-4360-b547-81e6249b0703'	System	24 Aug 2020 18:42:58
User entered '24 Aug 2020 13:42'	System	24 Aug 2020 18:42:58

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 6'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:11', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '13a4ebe4-5fa7-4a84-b089-cfbfb9f05367'	System	25 Aug 2020 21:33:24
User entered 'None (1)'	System	25 Aug 2020 21:33:24

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:13', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '13a4ebe4-5fa7-4a84-b089-cfbfb9f05367'	System	25 Aug 2020 21:33:24
User entered 'No (N)'	System	25 Aug 2020 21:33:24

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:16', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '13a4ebe4-5fa7-4a84-b089-cfbfb9f05367'	System	25 Aug 2020 21:33:24
User entered 'No (N)'	System	25 Aug 2020 21:33:24

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:18', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '13a4ebe4-5fa7-4a84-b089-cfbfb9f05367'	System	25 Aug 2020 21:33:24
User entered 'None (1)'	System	25 Aug 2020 21:33:24

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:22', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '13a4ebe4-5fa7-4a84-b089-cfbfb9f05367' User entered '25 Aug 2020 16:33'	System	25 Aug 2020 21:33:24
	System	25 Aug 2020 21:33:24

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 7'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:26', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '84735ed2-5eaf-4cbf-91b2-586440122365'	System	26 Aug 2020 20:19:42
User entered 'None (1)'	System	26 Aug 2020 20:19:42

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:28', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '84735ed2-5eaf-4cbf-91b2-586440122365'	System	26 Aug 2020 20:19:42
User entered 'No (N)'	System	26 Aug 2020 20:19:42

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:31', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '84735ed2-5eaf-4cbf-91b2-586440122365'	System	26 Aug 2020 20:19:42
User entered 'No (N)'	System	26 Aug 2020 20:19:42

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:34', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '84735ed2-5eaf-4cbf-91b2-586440122365'	System	26 Aug 2020 20:19:42
User entered 'None (1)'	System	26 Aug 2020 20:19:42

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:39', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '84735ed2-5eaf-4cbf-91b2-586440122365'	System	26 Aug 2020 20:19:42
User entered '26 Aug 2020 15:19'	System	26 Aug 2020 20:19:42

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:20', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd79f4eee-be7e-4a31-bcb3-04214087b822'	System	20 Aug 2020 18:17:47
User entered 'None (0)'	System	20 Aug 2020 18:17:47

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:22', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd79f4eee-be7e-4a31-bcb3-04214087b822'	System	20 Aug 2020 18:17:47
User entered 'None (0)'	System	20 Aug 2020 18:17:47

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:25', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd79f4eee-be7e-4a31-bcb3-04214087b822'	System	20 Aug 2020 18:17:47
User entered 'None (0)'	System	20 Aug 2020 18:17:47

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:28', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd79f4eee-be7e-4a31-bcb3-04214087b822'	System	20 Aug 2020 18:17:47
User entered 'None (0)'	System	20 Aug 2020 18:17:47

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:30', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd79f4eee-be7e-4a31-bcb3-04214087b822'	System	20 Aug 2020 18:17:47
User entered 'None (0)'	System	20 Aug 2020 18:17:47

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:32', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd79f4eee-be7e-4a31-bcb3-04214087b822'	System	20 Aug 2020 18:17:47
User entered 'None (0)'	System	20 Aug 2020 18:17:47

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:36', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd79f4eee-be7e-4a31-bcb3-04214087b822'	System	20 Aug 2020 18:17:47
User entered 'No (N)'	System	20 Aug 2020 18:17:47

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T13:17:45', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd79f4eee-be7e-4a31-bcb3-04214087b822'	System	20 Aug 2020 18:17:47
User entered '20 Aug 2020 13:17'	System	20 Aug 2020 18:17:47

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '20 Aug 2020 13:05'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '20 Aug 2020 15:35'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:11:43', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9385c76f-31ff-4478-9b8c-781ec50aa9f7'	System	21 Aug 2020 02:12:12
User entered 'None (0)'	System	21 Aug 2020 02:12:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:11:46', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9385c76f-31ff-4478-9b8c-781ec50aa9f7'	System	21 Aug 2020 02:12:12
User entered 'None (0)'	System	21 Aug 2020 02:12:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:11:50', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9385c76f-31ff-4478-9b8c-781ec50aa9f7'	System	21 Aug 2020 02:12:12
User entered 'None (0)'	System	21 Aug 2020 02:12:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:11:53', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9385c76f-31ff-4478-9b8c-781ec50aa9f7'	System	21 Aug 2020 02:12:12
User entered 'None (0)'	System	21 Aug 2020 02:12:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:11:56', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9385c76f-31ff-4478-9b8c-781ec50aa9f7'	System	21 Aug 2020 02:12:12
User entered 'None (0)'	System	21 Aug 2020 02:12:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:11:58', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9385c76f-31ff-4478-9b8c-781ec50aa9f7'	System	21 Aug 2020 02:12:12
User entered 'None (0)'	System	21 Aug 2020 02:12:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:12:01', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9385c76f-31ff-4478-9b8c-781ec50aa9f7'	System	21 Aug 2020 02:12:12
User entered 'No (N)'	System	21 Aug 2020 02:12:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-20T21:12:09', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9385c76f-31ff-4478-9b8c-781ec50aa9f7'	System	21 Aug 2020 02:12:12
User entered '20 Aug 2020 21:12'	System	21 Aug 2020 02:12:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '20 Aug 2020 16:30'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 2'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:39:37', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd3853df5-7c51-4780-a2ea-6d9ac062cc6a' User entered 'None (0)'	System	21 Aug 2020 17:40:14
	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:39:40', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd3853df5-7c51-4780-a2ea-6d9ac062cc6a' User entered 'None (0)'	System	21 Aug 2020 17:40:14
	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:39:42', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd3853df5-7c51-4780-a2ea-6d9ac062cc6a' User entered 'None (0)'	System	21 Aug 2020 17:40:14
	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:39:46', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd3853df5-7c51-4780-a2ea-6d9ac062cc6a' User entered 'None (0)'	System	21 Aug 2020 17:40:14
	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:40:01', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd3853df5-7c51-4780-a2ea-6d9ac062cc6a' User entered 'None (0)'	System	21 Aug 2020 17:40:14
	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:40:05', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd3853df5-7c51-4780-a2ea-6d9ac062cc6a' User entered 'None (0)'	System	21 Aug 2020 17:40:14
	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:40:09', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd3853df5-7c51-4780-a2ea-6d9ac062cc6a' User entered 'No (N)'	System	21 Aug 2020 17:40:14
	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:40:12', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd3853df5-7c51-4780-a2ea-6d9ac062cc6a' User entered '21 Aug 2020 12:40'	System	21 Aug 2020 17:40:14
	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 3'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:54', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7ecb28c1-a8f0-4648-9600-383dabeb8f6c' User entered 'None (0)'	System	22 Aug 2020 19:51:21
	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:57', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7ecb28c1-a8f0-4648-9600-383dabeb8f6c' User entered 'None (0)'	System	22 Aug 2020 19:51:21
	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:59', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7ecb28c1-a8f0-4648-9600-383dabeb8f6c' User entered 'None (0)'	System	22 Aug 2020 19:51:21
	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:51:01', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7ecb28c1-a8f0-4648-9600-383dabeb8f6c' User entered 'None (0)'	System	22 Aug 2020 19:51:21
	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:51:03', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7ecb28c1-a8f0-4648-9600-383dabeb8f6c' User entered 'None (0)'	System	22 Aug 2020 19:51:21
	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:51:05', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7ecb28c1-a8f0-4648-9600-383dabeb8f6c' User entered 'None (0)'	System	22 Aug 2020 19:51:21
	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:51:13', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7ecb28c1-a8f0-4648-9600-383dabeb8f6c' User entered 'No (N)'	System	22 Aug 2020 19:51:21
	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:51:20', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7ecb28c1-a8f0-4648-9600-383dabeb8f6c' User entered '22 Aug 2020 14:51'	System	22 Aug 2020 19:51:21
	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 4'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:23', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b8b8bfc6-000a-439d-9c75-0b349eed5bbb' User entered 'None (0)'	System	23 Aug 2020 17:42:49
	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:25', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b8b8bfc6-000a-439d-9c75-0b349eed5bbb' User entered 'None (0)'	System	23 Aug 2020 17:42:49
	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b8b8bfc6-000a-439d-9c75-0b349eed5bbb' User entered 'None (0)'	System	23 Aug 2020 17:42:49
	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:32', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b8b8bfc6-000a-439d-9c75-0b349eed5bbb' User entered 'None (0)'	System	23 Aug 2020 17:42:49
	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:35', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b8b8bfc6-000a-439d-9c75-0b349eed5bbb' User entered 'None (0)'	System	23 Aug 2020 17:42:49
	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:37', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b8b8bfc6-000a-439d-9c75-0b349eed5bbb' User entered 'None (0)'	System	23 Aug 2020 17:42:49
	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:40', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b8b8bfc6-000a-439d-9c75-0b349eed5bbb' User entered 'No (N)'	System	23 Aug 2020 17:42:49
	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:47', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b8b8bfc6-000a-439d-9c75-0b349eed5bbb' User entered '23 Aug 2020 12:42'	System	23 Aug 2020 17:42:49
	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 5'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:43:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '806c516e-e2bf-4db1-b828-fd202ed69e12' User entered 'None (0)'	System	24 Aug 2020 18:43:49
	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:43:32', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '806c516e-e2bf-4db1-b828-fd202ed69e12' User entered 'None (0)'	System	24 Aug 2020 18:43:49
	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:43:35', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '806c516e-e2bf-4db1-b828-fd202ed69e12' User entered 'None (0)'	System	24 Aug 2020 18:43:49
	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:43:37', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '806c516e-e2bf-4db1-b828-fd202ed69e12' User entered 'None (0)'	System	24 Aug 2020 18:43:49
	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:43:39', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '806c516e-e2bf-4db1-b828-fd202ed69e12' User entered 'None (0)'	System	24 Aug 2020 18:43:49
	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:43:42', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '806c516e-e2bf-4db1-b828-fd202ed69e12' User entered 'None (0)'	System	24 Aug 2020 18:43:49
	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:43:45', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '806c516e-e2bf-4db1-b828-fd202ed69e12'	System	24 Aug 2020 18:43:49
User entered 'No (N)'	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-24T13:43:48', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '806c516e-e2bf-4db1-b828-fd202ed69e12' User entered '24 Aug 2020 13:43'	System	24 Aug 2020 18:43:49
	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 6'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:26', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '00ffb9c4-5799-4f95-8a55-f50c65a22219' User entered 'None (0)'	System	25 Aug 2020 21:33:52
	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:28', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '00ffb9c4-5799-4f95-8a55-f50c65a22219' User entered 'None (0)'	System	25 Aug 2020 21:33:52
	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:32', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '00ffb9c4-5799-4f95-8a55-f50c65a22219' User entered 'None (0)'	System	25 Aug 2020 21:33:52
	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:35', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '00ffb9c4-5799-4f95-8a55-f50c65a22219' User entered 'None (0)'	System	25 Aug 2020 21:33:52
	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:38', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '00ffb9c4-5799-4f95-8a55-f50c65a22219' User entered 'None (0)'	System	25 Aug 2020 21:33:52
	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:40', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '00ffb9c4-5799-4f95-8a55-f50c65a22219' User entered 'None (0)'	System	25 Aug 2020 21:33:52
	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:43', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '00ffb9c4-5799-4f95-8a55-f50c65a22219' User entered 'No (N)'	System	25 Aug 2020 21:33:52
	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:50', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '00ffb9c4-5799-4f95-8a55-f50c65a22219' User entered '25 Aug 2020 16:33'	System	25 Aug 2020 21:33:52
	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 7'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:43', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'ed43caf1-91bc-4de6-8974-7ece3f5aa5ac' User entered 'None (0)'	System	26 Aug 2020 20:20:12
	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:45', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'ed43caf1-91bc-4de6-8974-7ece3f5aa5ac' User entered 'None (0)'	System	26 Aug 2020 20:20:12
	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:47', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'ed43caf1-91bc-4de6-8974-7ece3f5aa5ac' User entered 'None (0)'	System	26 Aug 2020 20:20:12
	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:50', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'ed43caf1-91bc-4de6-8974-7ece3f5aa5ac' User entered 'None (0)'	System	26 Aug 2020 20:20:12
	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:54', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'ed43caf1-91bc-4de6-8974-7ece3f5aa5ac' User entered 'None (0)'	System	26 Aug 2020 20:20:12
	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:19:57', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'ed43caf1-91bc-4de6-8974-7ece3f5aa5ac' User entered 'None (0)'	System	26 Aug 2020 20:20:12
	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:20:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'ed43caf1-91bc-4de6-8974-7ece3f5aa5ac'	System	26 Aug 2020 20:20:12
User entered 'No (N)'	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-26T15:20:09', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'ed43caf1-91bc-4de6-8974-7ece3f5aa5ac' User entered '26 Aug 2020 15:20'	System	26 Aug 2020 20:20:12
	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:48:27

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:51:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 19:41:18

US3552103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '27 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 19:41:18

US3552103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 19:41:18

US3552103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 19:41:18

US3552103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Sep 2020 21:14:56

US3552103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'l'	System	03 Sep 2020 21:14:56

US3552103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	03 Sep 2020 21:15:05

US3552103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered '03 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 13:35:25
User entered '3 Sep 2020'	Mikayla Frye (b) (4) (b) (4)	03 Sep 2020 21:15:05

US3552103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	03 Sep 2020 21:15:05

US3552103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered empty.	Mikayla Frye (b) (4) (b) (4)	03 Sep 2020 21:15:05

US3552103

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:48:35

US3552103

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'l'	System	22 Sep 2020 12:48:35

US3552103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:48:43

US3552103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	22 Sep 2020 12:49:23
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	22 Sep 2020 12:49:23
User entered '11 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	22 Sep 2020 12:49:23
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Sep 2020 12:48:43
User entered '21 Sep 2020'	Stanley Dublin (b) (4)	22 Sep 2020 12:48:43

US3552103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:48:43

US3552103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:48:43

US3552103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:51:22

US3552103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'l'	System	22 Sep 2020 12:51:22

US3552103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:51:34

US3552103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:51:34

US3552103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:51:34

US3552103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'VISIT2'	System	22 Sep 2020 12:51:34

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '16:05'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered '21 Sep 2020 16:05'	System	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '98.3' F	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '76'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'bpm'	System	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '22'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'breaths/min'	System	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '129'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'mmHg'	System	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '91'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'mmHg'	System	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:37

US3552103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:37

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User closed query 'As a reminder - please complete the Dosing Disct eCRF. ' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 15:22:56
Query 'As a reminder - please complete the Dosing Disct eCRF. ' answered with 'done' (Site from CRA).	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:58:02
User opened query 'As a reminder - please complete the Dosing Disct eCRF. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 15:46:43
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Physician Decision (PHYSICIAN DECISION)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User closed query 'Please verify is Worsening depression should be added as AE (qualifies as exacerbation of a chronic or intermittent pre-existing condition) ' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 15:22:54
Query 'Please verify is Worsening depression should be added as AE (qualifies as exacerbation of a chronic or intermittent pre-existing condition) ' answered with 'done' (Site from CRA).	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:58:08
User opened query 'Please verify is Worsening depression should be added as AE (qualifies as exacerbation of a chronic or intermittent pre-existing condition) ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:48:03
Query 'Please verify if worsening depression should be recorded as an AE (worsening condition from the baseline). ' canceled (Site from CRA).		23 Sep 2020 16:44:21
User opened query 'Please verify if worsening depression should be recorded as an AE (worsening condition from the baseline). ' (Site from CRA).		23 Sep 2020 15:53:03
Query 'Please verify if worsening depression should be recorded as a worsening condition from the baseline. ' canceled (Site from CRA).		23 Sep 2020 15:52:45
User opened query 'Please verify if worsening depression should be recorded as a worsening condition from the baseline. ' (Site from CRA).		23 Sep 2020 15:52:35
User entered 'worsening depression'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:56:52

US3552103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:56:52

US3552103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '16:50'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:56:52

US3552103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered '21 Sep 2020 16:50'	System	22 Sep 2020 12:56:52

US3552103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:57:05

US3552103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 12:57:05

US3552103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	22 Sep 2020 12:57:05

US3552103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '16:55'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:57:05

US3552103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered '21 Sep 2020 16:55'	System	22 Sep 2020 12:57:05

US3552103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 12:57:05

US3552103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:57:05

US3552103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Stanley Dublin (b) (4)	22 Sep 2020 12:57:05

US3552103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	22 Sep 2020 12:57:05

US3552103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 12:05:02

US3552103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'I'	System	29 Sep 2020 12:05:02

US3552103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 12:05:13

US3552103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '28 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 12:05:13

US3552103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 12:05:13

US3552103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 12:05:13

US3552103

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	06 Oct 2020 12:41:47

US3552103

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'l'	System	06 Oct 2020 12:41:47

US3552103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	06 Oct 2020 12:41:55

US3552103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered '05 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 13:35:43
User entered '5 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	06 Oct 2020 12:41:55

US3552103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	06 Oct 2020 12:41:55

US3552103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered empty.	Stanley Dublin (b) (4) (b) (4)	06 Oct 2020 12:41:55

US3552103

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:52:52

US3552103

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'l'	System	12 Oct 2020 17:52:52

US3552103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:53:14

US3552103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '12 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:53:14

US3552103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:53:14

US3552103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:53:14

US3552103

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:47

US3552103

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'l'	System	23 Oct 2020 16:37:47

US3552103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:54

US3552103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered '23 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:54

US3552103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:54

US3552103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'VISIT3'	System	23 Oct 2020 16:37:54

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered empty.	System	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00

US3552103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:38:02

US3552103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:38:02

US3552103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:38:18

US3552103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '23 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:38:18

US3552103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '10:28'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:38:18

US3552103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered '23 Oct 2020 10:28'	System	23 Oct 2020 16:38:18

US3552103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Nov 2020 15:09:52

US3552103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'I'	System	17 Nov 2020 15:09:52

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 64'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-10-23T10:39:50', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '3936f0c4-5a08-4607-8722-687e9e72553c' User entered 'No (N)'	System	23 Oct 2020 15:40:37
	System	23 Oct 2020 15:40:37

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-10-23T10:39:55', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '3936f0c4-5a08-4607-8722-687e9e72553c'	System	23 Oct 2020 15:40:37
User entered 'No (N)'	System	23 Oct 2020 15:40:37

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-10-23T10:40:32', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '3936f0c4-5a08-4607-8722-687e9e72553c' User entered '23 Oct 2020 10:40:32'	System	23 Oct 2020 15:40:37
	System	23 Oct 2020 15:40:37

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 71'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-10-27T00:06:13', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '20305de1-8618-4392-9238-e480225a754c'	System	27 Oct 2020 05:06:25
User entered 'No (N)'	System	27 Oct 2020 05:06:25

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-10-27T00:06:18', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '20305de1-8618-4392-9238-e480225a754c'	System	27 Oct 2020 05:06:25
User entered 'No (N)'	System	27 Oct 2020 05:06:25

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-10-27T00:06:23', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '20305de1-8618-4392-9238-e480225a754c' User entered '27 Oct 2020 00:06:23'	System	27 Oct 2020 05:06:25
	System	27 Oct 2020 05:06:25

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 78'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-06T04:47:30', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'cb7e255a-5a86-491e-b566-d03e575b2a1b' User entered 'Yes (Y)'	System	06 Nov 2020 10:49:01
	System	06 Nov 2020 10:49:01

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-06T04:47:37', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'cb7e255a-5a86-491e-b566-d03e575b2a1b' User entered 'No (N)'	System	06 Nov 2020 10:49:01
	System	06 Nov 2020 10:49:01

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-06T04:47:42', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'cb7e255a-5a86-491e-b566-d03e575b2a1b' User entered 'No (N)'	System	06 Nov 2020 10:49:01
	System	06 Nov 2020 10:49:01

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-06T04:48:04', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'cb7e255a-5a86-491e-b566-d03e575b2a1b' User entered 'No (N)'	System	06 Nov 2020 10:49:01
	System	06 Nov 2020 10:49:01

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-06T04:48:59', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'cb7e255a-5a86-491e-b566-d03e575b2a1b' User entered '06 Nov 2020 04:48:59'	System	06 Nov 2020 10:49:01
	System	06 Nov 2020 10:49:01

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered 'Day 92'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-17T00:01:49', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7def7a5a-8d02-4c1d-baa6-5ca6688c77cd' User entered 'No (N)'	System	17 Nov 2020 06:06:19
	System	17 Nov 2020 06:06:19

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-17T00:04:40', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7def7a5a-8d02-4c1d-baa6-5ca6688c77cd' User entered 'No (N)'	System	17 Nov 2020 06:06:19
	System	17 Nov 2020 06:06:19

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-17T00:06:12', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7def7a5a-8d02-4c1d-baa6-5ca6688c77cd' User entered '17 Nov 2020 00:06:12'	System	17 Nov 2020 06:06:19
	System	17 Nov 2020 06:06:19

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 17:48:27

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:56:33
Data entry locked.	System	20 Aug 2020 17:48:27
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 17:48:27

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-25T18:34:19', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '52520ae0-38d4-4996-a138-48da79267d02'	System	25 Nov 2020 23:34:52
User entered 'No (N)'	System	25 Nov 2020 23:34:52

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-25T18:34:41', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '52520ae0-38d4-4996-a138-48da79267d02'	System	25 Nov 2020 23:34:52
User entered 'No (N)'	System	25 Nov 2020 23:34:52

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-25T18:34:48', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '52520ae0-38d4-4996-a138-48da79267d02' User entered '25 Nov 2020 18:34:48'	System	25 Nov 2020 23:34:52
	System	25 Nov 2020 23:34:52

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-28T01:00:58', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9165b2bd-a7f1-48f3-a89f-7f33289392b9' User entered 'No (N)'	System	28 Nov 2020 06:01:22

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-28T01:01:09', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9165b2bd-a7f1-48f3-a89f-7f33289392b9' User entered 'No (N)'	System	28 Nov 2020 06:01:22

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-28T01:01:13', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '9165b2bd-a7f1-48f3-a89f-7f33289392b9' User entered '28 Nov 2020 01:01:13'	System	28 Nov 2020 06:01:22
	System	28 Nov 2020 06:01:22

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-05T21:14:25', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '48308442-3ae2-4498-8647-d9102e9d04e3'	System	06 Dec 2020 03:15:23
User entered 'No (N)'	System	06 Dec 2020 03:15:23

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-05T21:14:31', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '48308442-3ae2-4498-8647-d9102e9d04e3'	System	06 Dec 2020 03:15:23
User entered 'No (N)'	System	06 Dec 2020 03:15:23

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-05T21:15:20', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '48308442-3ae2-4498-8647-d9102e9d04e3' User entered '05 Dec 2020 21:15:20'	System	06 Dec 2020 03:15:23
	System	06 Dec 2020 03:15:23

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-12T10:42:40', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e5e06d76-ef9f-437f-bf91-909e339bbe2a' User entered 'No (N)'	System	12 Dec 2020 16:42:53

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-12T10:42:46', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e5e06d76-ef9f-437f-bf91-909e339bbe2a' User entered 'No (N)'	System	12 Dec 2020 16:42:53

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-12T10:42:50', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e5e06d76-ef9f-437f-bf91-909e339bbe2a' User entered '12 Dec 2020 10:42:50'	System	12 Dec 2020 16:42:53
	System	12 Dec 2020 16:42:53

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-21T10:55:18', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'f2fe7faf-4a9a-4f41-ac14-83622608356b' User entered 'No (N)'	System	21 Dec 2020 16:55:33
	System	21 Dec 2020 16:55:33

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-21T10:55:22', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'f2fe7faf-4a9a-4f41-ac14-83622608356b' User entered 'No (N)'	System	21 Dec 2020 16:55:33

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-21T10:55:28', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'f2fe7faf-4a9a-4f41-ac14-83622608356b' User entered '21 Dec 2020 10:55:28'	System	21 Dec 2020 16:55:33
	System	21 Dec 2020 16:55:33

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:09:17', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2'	System	28 Dec 2020 10:11:03
User entered 'Yes (Y)'	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:09:23', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2'	System	28 Dec 2020 10:11:03
User entered 'Yes (Y)'	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:09:32', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2'	System	28 Dec 2020 10:11:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:09:40', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2'	System	28 Dec 2020 10:11:03
User entered 'Yes (Y)'	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcae5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '1'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcae5-00b4-44fd-8758-7bb7e8ada8a2' User entered '1'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcae5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcae5-00b4-44fd-8758-7bb7e8ada8a2' User entered '1'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '1'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcae5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '1'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcae5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcae5-00b4-44fd-8758-7bb7e8ada8a2' User entered '1'	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:29', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '0'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:34', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2'	System	28 Dec 2020 10:11:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:42', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered 'No (N)'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-12-28T04:10:55', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '4fcaebc5-00b4-44fd-8758-7bb7e8ada8a2' User entered '28 Dec 2020 04:10:55'	System	28 Dec 2020 10:11:03
	System	28 Dec 2020 10:11:03

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-02T00:05:39', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e26f4f34-0462-453a-8460-729c3f47b98a' User entered 'No (N)'	System	02 Jan 2021 06:06:30
	System	02 Jan 2021 06:06:30

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-02T00:05:45', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e26f4f34-0462-453a-8460-729c3f47b98a' User entered 'No (N)'	System	02 Jan 2021 06:06:30
	System	02 Jan 2021 06:06:30

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-02T00:06:24', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e26f4f34-0462-453a-8460-729c3f47b98a' User entered '02 Jan 2021 00:06:24'	System	02 Jan 2021 06:06:30
	System	02 Jan 2021 06:06:30

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-09T23:07:44', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'fb07b564-45c0-43e7-b869-4a40ce132a65' User entered 'No (N)'	System	10 Jan 2021 05:07:55
	System	10 Jan 2021 05:07:55

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-09T23:07:46', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'fb07b564-45c0-43e7-b869-4a40ce132a65'	System	10 Jan 2021 05:07:55
User entered 'No (N)'	System	10 Jan 2021 05:07:55

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-09T23:07:52', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'fb07b564-45c0-43e7-b869-4a40ce132a65' User entered '09 Jan 2021 23:07:52'	System	10 Jan 2021 05:07:55
	System	10 Jan 2021 05:07:55

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-17T18:29:22', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '8b529481-716a-4bf8-8931-e6cdca61ed50' User entered 'No (N)'	System	18 Jan 2021 00:29:59
	System	18 Jan 2021 00:29:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-17T18:29:28', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '8b529481-716a-4bf8-8931-e6cdca61ed50' User entered 'No (N)'	System	18 Jan 2021 00:29:59
	System	18 Jan 2021 00:29:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-17T18:29:56', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '8b529481-716a-4bf8-8931-e6cdca61ed50' User entered '17 Jan 2021 18:29:56'	System	18 Jan 2021 00:29:59
	System	18 Jan 2021 00:29:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-24T23:30:21', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '837c7fcf-540c-4342-b86e-cc9a7d0f9334'	System	25 Jan 2021 05:31:10
User entered 'No (N)'	System	25 Jan 2021 05:31:10

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-24T23:30:28', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '837c7fcf-540c-4342-b86e-cc9a7d0f9334'	System	25 Jan 2021 05:31:10
User entered 'No (N)'	System	25 Jan 2021 05:31:10

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-24T23:30:59', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '837c7fcf-540c-4342-b86e-cc9a7d0f9334' User entered '24 Jan 2021 23:30:59'	System	25 Jan 2021 05:31:10
	System	25 Jan 2021 05:31:10

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-31T17:04:26', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '79029b28-833d-455f-b166-207be548400d' User entered 'No (N)'	System	31 Jan 2021 23:07:36

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-31T17:04:36', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '79029b28-833d-455f-b166-207be548400d' User entered 'No (N)'	System	31 Jan 2021 23:07:36

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-01-31T17:04:41', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '79029b28-833d-455f-b166-207be548400d' User entered '31 Jan 2021 17:04:41'	System	31 Jan 2021 23:07:36
	System	31 Jan 2021 23:07:36

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-02-08T12:25:14', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e17afee3-d85a-4534-98da-6b4d1e9f69c0'	System	08 Feb 2021 18:25:56
User entered 'No (N)'	System	08 Feb 2021 18:25:56

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-02-08T12:25:20', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e17afee3-d85a-4534-98da-6b4d1e9f69c0'	System	08 Feb 2021 18:25:56
User entered 'No (N)'	System	08 Feb 2021 18:25:56

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-02-08T12:25:50', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e17afec3-d85a-4534-98da-6b4d1e9f69c0'	System	08 Feb 2021 18:25:56
User entered '08 Feb 2021 12:25:50'	System	08 Feb 2021 18:25:56

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-02-13T08:10:52', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e719470c-580d-44ad-85ef-2493191cf39d' User entered 'No (N)'	System	13 Feb 2021 14:11:12

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-02-13T08:11:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e719470c-580d-44ad-85ef-2493191cf39d' User entered 'No (N)'	System	13 Feb 2021 14:11:12
	System	13 Feb 2021 14:11:12

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-02-13T08:11:08', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'e719470c-580d-44ad-85ef-2493191cf39d'	System	13 Feb 2021 14:11:12
User entered '13 Feb 2021 08:11:08'	System	13 Feb 2021 14:11:12

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-02-22T12:39:50', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'a988bdda-29bb-472c-ab41-d73b4644f89f' User entered 'No (N)'	System	25 Feb 2021 22:03:58
	System	25 Feb 2021 22:03:58

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-02-22T12:39:54', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'a988bdda-29bb-472c-ab41-d73b4644f89f' User entered 'No (N)'	System	25 Feb 2021 22:03:58
	System	25 Feb 2021 22:03:58

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-02-22T12:40:27', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'a988bdda-29bb-472c-ab41-d73b4644f89f' User entered '22 Feb 2021 12:40:27'	System	25 Feb 2021 22:03:58
	System	25 Feb 2021 22:03:58

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-01T05:06:01-06:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'aa692741-5476-4ea2-9305-7760f8b97cae' User entered 'No (N)'	System	01 Mar 2021 11:06:12

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-01T05:06:05-06:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'aa692741-5476-4ea2-9305-7760f8b97cae' User entered 'No (N)'	System	01 Mar 2021 11:06:12
	System	01 Mar 2021 11:06:12

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-01T05:06:10-06:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'aa692741-5476-4ea2-9305-7760f8b97cae' User entered '01 Mar 2021 05:06:10'	System	01 Mar 2021 11:06:12
	System	01 Mar 2021 11:06:12

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-06T15:18:34-06:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'a21b072d-d914-42bd-8618-0ed3875c50e7'	System	06 Mar 2021 21:18:48
User entered 'No (N)'	System	06 Mar 2021 21:18:48

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-06T15:18:37-06:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'a21b072d-d914-42bd-8618-0ed3875c50e7'	System	06 Mar 2021 21:18:48
User entered 'No (N)'	System	06 Mar 2021 21:18:48

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-06T15:18:42-06:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'a21b072d-d914-42bd-8618-0ed3875c50e7' User entered '06 Mar 2021 15:18:42'	System	06 Mar 2021 21:18:48
	System	06 Mar 2021 21:18:48

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-15T06:16:29-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '59a3e849-513e-430a-96f2-5f8b9ef15a29'	System	15 Mar 2021 11:17:08
User entered 'No (N)'	System	15 Mar 2021 11:17:08

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-15T06:16:40-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '59a3e849-513e-430a-96f2-5f8b9ef15a29'	System	15 Mar 2021 11:17:08
User entered 'No (N)'	System	15 Mar 2021 11:17:08

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-15T06:17:05-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '59a3e849-513e-430a-96f2-5f8b9ef15a29' User entered '15 Mar 2021 06:17:05'	System	15 Mar 2021 11:17:08
	System	15 Mar 2021 11:17:08

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-22T13:27:27-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '3469473b-64d7-4a3a-a692-10877ff12c3c'	System	22 Mar 2021 18:28:02
User entered 'No (N)'	System	22 Mar 2021 18:28:02

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-22T13:27:31-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '3469473b-64d7-4a3a-a692-10877ff12c3c' User entered 'No (N)'	System	22 Mar 2021 18:28:02

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-22T13:27:59-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '3469473b-64d7-4a3a-a692-10877ff12c3c' User entered '22 Mar 2021 13:27:59'	System	22 Mar 2021 18:28:02
	System	22 Mar 2021 18:28:02

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-27T15:06:11-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b56c0a71-e65c-4481-9264-cd4b902cc4c9' User entered 'No (N)'	System	27 Mar 2021 20:07:20
	System	27 Mar 2021 20:07:20

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-27T15:07:11-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b56c0a71-e65c-4481-9264-cd4b902cc4c9' User entered 'No (N)'	System	27 Mar 2021 20:07:20
	System	27 Mar 2021 20:07:20

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-27T15:07:16-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b56c0a71-e65c-4481-9264-cd4b902cc4c9' User entered '27 Mar 2021 15:07:16'	System	27 Mar 2021 20:07:20
	System	27 Mar 2021 20:07:20

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-03T16:32:20-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '296df439-318a-4867-8d81-df1f86821f54'	System	05 Apr 2021 00:14:13
User entered 'No (N)'	System	05 Apr 2021 00:14:13

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-03T16:32:26-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '296df439-318a-4867-8d81-df1f86821f54'	System	05 Apr 2021 00:14:13
User entered 'Yes (Y)'	System	05 Apr 2021 00:14:13

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-04T19:13:52-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '296df439-318a-4867-8d81-df1f86821f54'	System	05 Apr 2021 00:14:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Apr 2021 00:14:13

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-04T19:13:58-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '296df439-318a-4867-8d81-df1f86821f54'	System	05 Apr 2021 00:14:13
User entered '04 Apr 2021 19:13:58'	System	05 Apr 2021 00:14:13

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-10T00:03:00-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'c835b30d-fdfc-4535-ae50-bbe442dd7471' User entered 'No (N)'	System	10 Apr 2021 05:03:32

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-10T00:03:05-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'c835b30d-fdfc-4535-ae50-bbe442dd7471' User entered 'Yes (Y)'	System	10 Apr 2021 05:03:32
	System	10 Apr 2021 05:03:32

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-10T00:03:08-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'c835b30d-fdfc-4535-ae50-bbe442dd7471'	System	10 Apr 2021 05:03:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Apr 2021 05:03:32

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-10T00:03:13-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'c835b30d-fdfc-4535-ae50-bbe442dd7471'	System	10 Apr 2021 05:03:32
User entered '10 Apr 2021 00:03:13'	System	10 Apr 2021 05:03:32

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-17T16:34:30-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b7190454-3efc-4dee-b242-6d04ee2c8fd3'	System	17 Apr 2021 21:34:40
User entered 'No (N)'	System	17 Apr 2021 21:34:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-17T16:34:33-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b7190454-3efc-4dee-b242-6d04ee2c8fd3' User entered 'No (N)'	System	17 Apr 2021 21:34:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-17T16:34:37-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b7190454-3efc-4dee-b242-6d04ee2c8fd3'	System	17 Apr 2021 21:34:40
User entered '17 Apr 2021 16:34:37'	System	17 Apr 2021 21:34:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-26T12:00:18-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '86230b97-5d6f-46c2-906f-d31c585039e8' User entered 'No (N)'	System	26 Apr 2021 17:00:49
	System	26 Apr 2021 17:00:49

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-26T12:00:23-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '86230b97-5d6f-46c2-906f-d31c585039e8' User entered 'No (N)'	System	26 Apr 2021 17:00:49
	System	26 Apr 2021 17:00:49

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-04-26T12:00:27-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '86230b97-5d6f-46c2-906f-d31c585039e8' User entered '26 Apr 2021 12:00:27'	System	26 Apr 2021 17:00:49
	System	26 Apr 2021 17:00:49

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-05-01T00:21:25-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'a3216880-e7c0-4b59-a70f-1aa6a26d28f9'	System	01 May 2021 05:29:37
User entered 'No (N)'	System	01 May 2021 05:29:37

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-05-01T00:21:27-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'a3216880-e7c0-4b59-a70f-1aa6a26d28f9'	System	01 May 2021 05:29:37
User entered 'No (N)'	System	01 May 2021 05:29:37

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-05-01T00:21:31-05:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'a3216880-e7c0-4b59-a70f-1aa6a26d28f9' User entered '01 May 2021 00:21:31'	System	01 May 2021 05:29:37
	System	01 May 2021 05:29:37

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:53:40

US3552103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:51:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:05:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-01T05:05:50-06:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b7fb9da2-9b42-4113-afa5-e5d0b7669732'	System	01 Mar 2021 11:05:56
User entered 'No (N)'	System	01 Mar 2021 11:05:56

US3552103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:51:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:05:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2021-03-01T05:05:55-06:00', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b7fb9da2-9b42-4113-afa5-e5d0b7669732' User entered '01 Mar 2021 05:05:55'	System	01 Mar 2021 11:05:56
	System	01 Mar 2021 11:05:56

US3552103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Nov 2020 15:10:09

US3552103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered '17 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Nov 2020 15:10:09

US3552103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	17 Nov 2020 15:10:09

US3552103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:58
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Nov 2020 15:10:09

US3552103

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:58
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Dec 2020 13:14:39

US3552103

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:45:00
User entered 'l'	System	22 Dec 2020 13:14:39

US3552103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Dec 2020 13:14:49

US3552103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '21 Dec 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Dec 2020 13:14:49

US3552103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Dec 2020 13:14:49

US3552103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Dec 2020 13:14:49

US3552103

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 14:57:31

US3552103

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered 'l'	System	25 Jan 2021 14:57:31

US3552103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 14:57:47

US3552103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '22 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 14:57:47

US3552103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 14:57:47

US3552103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	25 Jan 2021 14:57:47

US3552103

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	12 Feb 2021 19:15:47

US3552103

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered 'l'	System	12 Feb 2021 19:15:47

US3552103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:19:32
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 16:28:02

US3552103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:19:32
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 16:28:02

US3552103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:19:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 16:28:02

US3552103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:19:32
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 16:28:02

US3552103

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:19:32
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 16:28:06

US3552103

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered 'l'	System	22 Feb 2021 16:28:06

US3552103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:27:54

US3552103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '22 Mar 2021'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:27:54

US3552103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered 'Clinic (Clinic)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:27:54

US3552103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered 'VISIT4'	System	22 Mar 2021 21:27:54

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
	(b) (4)	
User entered 'No (N)'	Cassandra Zehenny (b) (4)	29 Mar 2021 15:34:43
	(b) (4)	

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
	(b) (4)	
User entered '22 Mar 2021' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 15:34:43
	(b) (4)	

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
User entered '14:03' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 15:34:43
	(b) (4)	

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered '22 Mar 2021 14:03'	System	30 Mar 2021 19:37:21
User entered empty.	System	29 Mar 2021 15:34:43

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
	(b) (4)	
User entered '98.9' F reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 15:34:43
	(b) (4)	

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
User entered 'Oral (Oral)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 15:34:43
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:21:13
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 15:34:43

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
User entered '75' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 15:34:43
	(b) (4)	

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered 'bpm'	System	30 Mar 2021 19:37:21
User entered empty.	System	29 Mar 2021 15:34:43

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
	(b) (4)	
User entered '16' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 15:34:43
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered 'breaths/min'	System	30 Mar 2021 19:37:21
User entered empty.	System	29 Mar 2021 15:34:43

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
User entered '128' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 15:34:43
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered 'mmHg'	System	30 Mar 2021 19:37:21
User entered empty.	System	29 Mar 2021 15:34:43

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
	(b) (4)	
User entered '82' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:21
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 15:34:43
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered 'mmHg'	System	30 Mar 2021 19:37:21
User entered empty.	System	29 Mar 2021 15:34:43

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28

US3552103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28

US3552103

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
User closed query 'Per CDM RQ: Thank you for the response. Please complete all the required fields and if confirmed the visits occurred on the same, data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 04:25:20
Signature has been broken.	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:35
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
Query 'Per CDM RQ: Thank you for the response. Please complete all the required fields and if confirmed the visits occurred on the same, data must match. Please review and reconcile.' answered with 'These visits are not the same and therefore the data cannot match. Data correct as entered.' (Site from DM).	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:35
	(b) (4)	
Query 'Per CDM RQ: Thank you for the response. Please complete all the required fields and if confirmed the visits occurred on the same, data must match. Please review and reconcile.' answered with 'These visits are not the same and therefore the data cannot match. Data correct as entered.' (Site from DM).	Cassandra Zehenny (b) (4)	30 Mar 2021 16:40:11
	(b) (4)	
User opened query 'Per CDM RQ: Thank you for the response. Please complete all the required fields and if confirmed the visits occurred on the same, data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:51:09
User closed query 'Per CDM: Visit 4 Day 209 and OL-Day29 are both dated 22Mar2021. However, the data on the Physical examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile' (Site from DM).		30 Mar 2021 12:51:09
Query 'Per CDM: Visit 4 Day 209 and OL-Day29 are both dated 22Mar2021. However, the data on the Physical examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile' answered with 'PE done for OL-D29, not V4. Entered correctly, the same way we did with vital signs for Screening Visit and Visit Day 1 in the beginning of the study.' (Site from DM).	Cassandra Zehenny (b) (4)	29 Mar 2021 15:34:37
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Visit 4 Day 209 and OL-Day29 are both dated 22Mar2021. However, the data on the Physical examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 05:55:18
User entered 'No (N)'	sharon frey (b) (4) (b) (4) Cassandra Zehenny (b) (4) (b) (4)	23 Mar 2021 15:24:47 22 Mar 2021 21:29:13

US3552103

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:35
	(b) (4)	
User entered '22 Mar 2021' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 19:37:35
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	22 Mar 2021 21:29:13
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:29:24

US3552103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '22 Mar 2021'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:29:24

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '14:16'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:29:24

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered '22 Mar 2021 14:16'	System	22 Mar 2021 21:29:24

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:27:40

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:28
User entered 'l'	System	22 Mar 2021 21:27:40

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 16:13:23

US3552103

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered '19 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 16:13:23

US3552103

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 16:13:23

US3552103

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Apr 2021 16:13:23

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 16:13:26

US3552103

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 16:13:26

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

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:51:43

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

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4)	
Stanley Doublin	(b) (4)	26 Feb 2021 13:42:43
Signature has been broken.	(b) (4)	
Stanley Doublin	(b) (4)	26 Feb 2021 13:41:43
User entered '25 Feb 2021' reason for change: Data Entry Error	(b) (4)	
Stanley Doublin	(b) (4)	26 Feb 2021 13:41:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '12 Jan 2021'	(b) (4)	
Cassandra Zehenny	(b) (4)	13 Jan 2021 15:51:43
(b) (4)		

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

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Clinic (Clinic)'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:51:43

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

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 15:51:43

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered '12 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:52:02

US3552103

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:10:35

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) System	13 Jan 2021 15:52:08
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	13 Jan 2021 15:52:08
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	13 Jan 2021 15:52:02
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:52:02

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:10:35

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered '12 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:52:02

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Placebo (Placebo)'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:52:02

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 12:25:36
User entered 'Placebo (Placebo)'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:52:02

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:19:32
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	24 Feb 2021 19:07:39
	(b) (4)	
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Heather Douds (b) (4)	24 Feb 2021 19:07:39
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 12:25:36
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	13 Jan 2021 15:52:08
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	13 Jan 2021 15:52:02
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
Signature has been broken.	(b) (4)	
	Stanley Doublin (b) (4)	26 Feb 2021 13:42:22
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	26 Feb 2021 13:42:22
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
	(b) (4)	
User entered 'No (N)'	Cassandra Zehenny (b) (4)	13 Jan 2021 15:52:02
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'I'	System	13 Jan 2021 15:52:08
User entered empty.	System	13 Jan 2021 15:52:02

US3552103

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

Form: Unblinding

Generated On: 11 Aug 2021 22:51:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'I'	System	26 Feb 2021 13:42:22
User entered empty.	System	13 Jan 2021 15:52:02

US3552103

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	26 Feb 2021 13:43:30
DataPoint set to visible.	System	26 Feb 2021 13:42:22

US3552103

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	26 Feb 2021 13:43:30
DataPoint set to visible.	System	26 Feb 2021 13:42:22

US3552103

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '25 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '15:25' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 13:44:22
User entered '16:15'	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 13:43:30
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '25 Feb 2021 15:25'	System	26 Feb 2021 13:44:22
User entered '25 Feb 2021 16:15'	System	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '98.5' F reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 13:44:22
User entered '97.9' F	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 13:43:30
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '93' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 13:44:22
User entered '84'	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 13:43:30
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'bpm'	System	26 Feb 2021 13:43:30

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'breaths/min'	System	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '143' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 13:44:22
User entered '122'	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 13:43:30
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'mmHg'	System	26 Feb 2021 13:43:30

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '91' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 13:44:22
User entered '81'	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 13:43:30
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'mmHg'	System	26 Feb 2021 13:43:30

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

US3552103

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:43:30

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered empty.	System	26 Feb 2021 13:43:30
DataPoint set to visible.	System	26 Feb 2021 13:42:22

US3552103

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '25 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '16:15'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '25 Feb 2021 16:15'	System	26 Feb 2021 13:44:46

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:53:50
User entered '97.9' F	Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

US3552103

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '84'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

US3552103

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'bpm'	System	26 Feb 2021 13:44:46

US3552103

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

US3552103

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'breaths/min'	System	26 Feb 2021 13:44:46

US3552103

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '122'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'mmHg'	System	26 Feb 2021 13:44:46

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '81'	(b) (4) Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 13:44:46

US3552103

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'mmHg'	System	26 Feb 2021 13:44:46

US3552103

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:47:06

US3552103

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '25 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:47:06

US3552103

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 13:47:57

US3552103

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:47:57

US3552103

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:47:57

US3552103

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'mRNA-1273'	System	26 Feb 2021 13:47:57
DataPoint set to visible.	System	26 Feb 2021 13:42:22

US3552103

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '25 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:47:57

US3552103

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered '15:45'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:47:57

US3552103

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '25 Feb 2021 15:45'	System	26 Feb 2021 13:47:57

US3552103

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:47:57

US3552103

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'ONCE'	System	26 Feb 2021 13:47:57

US3552103

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

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 13:47:57

US3552103

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:52:59

US3552103

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User closed query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	26 Feb 2021 13:42:43
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	26 Feb 2021 13:41:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '12 Jan 2021'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:52:59

US3552103

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered '13:40'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:52:59

US3552103

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '12 Jan 2021 13:40'	System	13 Jan 2021 15:52:59

US3552103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:53:12

US3552103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered '12 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:53:12

US3552103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered '13:45'	Cassandra Zehenny (b) (4) (b) (4)	13 Jan 2021 15:53:12

US3552103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:43

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered '12 Jan 2021 13:45'	System	13 Jan 2021 15:53:12

US3552103

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

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:53:50
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 13:48:05

US3552103

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

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:03
User entered 'I'	System	26 Feb 2021 13:48:05

US3552103

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:53
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:53:44
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Mar 2021 19:24:48

US3552103

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:53
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:53:44
User entered '4 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Mar 2021 19:24:48

US3552103

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:53
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:53:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4)	04 Mar 2021 19:24:48

US3552103

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:53
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:53:44
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Mar 2021 19:24:48

US3552103

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:53
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:53:44
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Mar 2021 19:24:53

US3552103

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:53
User entered 'l'	System	04 Mar 2021 19:24:53

US3552103

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:53
User entered 'I'	System	04 Mar 2021 19:24:53
DataPoint set to visible.	System	04 Mar 2021 19:24:53

US3552103

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:29:32

US3552103

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '22 Mar 2021'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:29:32

US3552103

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered 'Clinic (Clinic)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:29:32

US3552103

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'OLD29'	System	22 Mar 2021 21:29:32

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User accepted default value 'Pre-Dose (PREDOSE)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '22 Mar 2021'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered '14:03'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered '22 Mar 2021 14:03'	System	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '98.9' F	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered 'Oral (Oral)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered '75'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'bpm'	System	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '16'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'breaths/min'	System	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered '128'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'mmHg'	System	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '82'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'mmHg'	System	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User accepted default value 'Post-Dose (POSTDOSE)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '22 Mar 2021'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered '15:29'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered '22 Mar 2021 15:29'	System	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '98.4' F	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered 'Oral (Oral)'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered '76'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'bpm'	System	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '18'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'breaths/min'	System	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '128'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'mmHg'	System	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '82'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'mmHg'	System	22 Mar 2021 21:31:04

US3552103

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:11

US3552103

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '22 Mar 2021'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:11

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:26

US3552103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:26

US3552103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:26

US3552103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'mRNA-1273'	System	22 Mar 2021 21:31:26
DataPoint set to visible.	System	04 Mar 2021 19:24:53

US3552103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered '22 Mar 2021'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:26

US3552103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:24:47
User entered '14:59'	Cassandra Zehenny (b) (4) (b) (4)	22 Mar 2021 21:31:26

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered '22 Mar 2021 14:59'	System	22 Mar 2021 21:31:26

US3552103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:26

US3552103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'ONCE'	System	22 Mar 2021 21:31:26

US3552103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'INTRAMUSCULAR'	System	22 Mar 2021 21:31:26

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:24:47
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	22 Mar 2021 21:31:30

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:49
User entered 'l'	System	22 Mar 2021 21:31:30

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 18:14:56

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
User entered '29 Mar 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 18:14:56

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 18:14:56

US3552103

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 18:14:56

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:21:07
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 18:14:59

US3552103

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Mar 2021 18:14:59

US3552103

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:46

US3552103

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered '16 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:46

US3552103

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:46

US3552103

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:43

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	19 Apr 2021 13:15:46

US3552103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:50

US3552103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Apr 2021 13:15:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 13:15:50

US3552103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:50

US3552103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:50

US3552103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 13:15:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 13:15:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 13:15:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 13:15:50

US3552103

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Apr 2021 13:15:54

US3552103

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:15:54

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:16:05

US3552103

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered '16 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:16:05

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered '14:16'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:16:05

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Apr 2021 14:16'	System	19 Apr 2021 13:16:05

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:51:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:29:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:58:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 17:06:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 17:06:41
Data point term sent to Coder	System	23 Sep 2020 17:06:00
User entered 'Worsening depression'	Heather Douds (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	10 Nov 2020 13:36:09
User entered '3 Sep 2020'	(b) (4)	
	Heather Douds (b) (4)	23 Sep 2020 17:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Stanley Doublin (b) (4)	17 Nov 2020 15:11:13
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:11:13
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	23 Sep 2020 17:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	(b) (4) System	23 Sep 2020 19:45:26
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 19:39:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 19:39:01
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:39:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	23 Sep 2020 19:39:01
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 17:05:08
User entered empty.	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	23 Sep 2020 19:39:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 19:39:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	23 Sep 2020 19:39:01
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 17:05:08
User entered empty.	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' (Site from CRA).	(b) (4)	
Query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 15:15:37
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 15:15:31
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 01:38:22
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Heather Douds (b) (4)	23 Sep 2020 19:45:26
	(b) (4)	
	Heather Douds (b) (4)	23 Sep 2020 17:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Stanley Doublin (b) (4)	17 Nov 2020 15:11:13
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:51:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 17:05:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 16:35:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Choroid and vitreous structural change, deposit and degeneration, PT: Vitreous floaters, LLT: Myodesopsia - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 19:02:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 19:02:03
Data point term sent to Coder	System	19 Jan 2021 22:31:49
User entered 'right myodesopsia'	Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '08 Jan 2021'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User entered empty.	System	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:19:32
Signature has been broken.	(b) (4)	
	Stanley Doublin (b) (4)	22 Feb 2021 16:28:53
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Feb 2021 16:28:53
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
	(b) (4)	
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:19:32
Signature has been broken.	(b) (4)	
	Stanley Doublin (b) (4)	22 Feb 2021 16:28:53
	(b) (4)	
User entered '12 Feb 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Feb 2021 16:28:53
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User entered empty.	System	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'l'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:19:32
Signature has been broken.	(b) (4)	
	Stanley Doublin (b) (4)	22 Feb 2021 16:28:53
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Stanley Doublin (b) (4)	22 Feb 2021 16:28:53
Data Entry Error	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User entered '0'	System	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:06
User entered 'I'	System	19 Jan 2021 22:31:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 16:35:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:29:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:23:20

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 20:26:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 20:26:23
Data point term sent to Coder	System	20 Aug 2020 20:25:14
User entered 'Wellbutrin'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'depression'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '450' reason for change: New Information	(b) (4) Mikayla Frye (b) (4)	03 Sep 2020 21:15:52
User entered '300'	(b) (4) Mikayla Frye (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:54:56
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 with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4)	20 Aug 2020 20:34:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:24:39
User entered 'un UNK 2004'	Mikayla Frye (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 20:27:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 20:27:24
Data point term sent to Coder	System	20 Aug 2020 20:26:15
User entered 'Dicyclomine'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Irritable bowel syndrome'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '20'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'four times daily (QID)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:54:56
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 with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4)	20 Aug 2020 20:34:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:25:36
User entered 'un UNK 2018'	Mikayla Frye (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 06:45:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:45:14
Data point term sent to Coder	System	20 Aug 2020 20:27:22
User entered 'Lorazepam'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:57:59
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'corrected' (Site from DM).	Joan Siegner (b) (4)	30 Sep 2020 16:18:24
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:19:50
User entered 'Anxiety with heights'	Mikayla Frye (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0.5'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'as needed (PRN)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System (b) (4)	21 Aug 2020 05:54:56
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 with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4)	20 Aug 2020 20:34:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:26:48
User entered 'un UNK 2017'	Mikayla Frye (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Jan 2021 22:36:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 22:36:15
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	19 Jan 2021 22:34:55 19 Jan 2021 22:34:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 15:47:47
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 15:47:47
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4)	17 Nov 2020 15:46:18 17 Nov 2020 15:46:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 20:29:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 20:29:30
Data point term sent to Coder User entered 'Tylenol'	System Mikayla Frye (b) (4)	20 Aug 2020 20:28:25 20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF(NECK MUSCLE PAIN). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 11:25:17
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF(NECK MUSCLE PAIN). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	19 Jan 2021 22:34:06
User entered 'HEADACHES AND degenerative disc disease' reason for change: New Information	Cassandra Zehenny (b) (4)	19 Jan 2021 22:34:00
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF(NECK MUSCLE PAIN). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 05:13:18
User closed query 'Per DM CLR: Please update the indication to specify the location of MUSCLE PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	18 Nov 2020 13:07:49
' (Site from DM).		
User entered 'HEADACHES AND neck MUSCLE PAIN' reason for change: New Information	Heather Douds (b) (4)	17 Nov 2020 15:46:15
Query 'Per DM CLR: Please update the indication to specify the location of MUSCLE PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	26 Oct 2020 15:15:29
' answered with 'Will clarify on day 85 call' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to specify the location of MUSCLE PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.		22 Oct 2020 18:19:49
' (Site from DM).		
User entered 'Headaches and muscle pain'	Mikayla Frye (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 11:25:24
User entered '500' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	19 Jan 2021 22:34:10
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	
User entered '300'	Cassandra Zehenny (b) (4)	19 Jan 2021 22:34:00
	(b) (4), (b) (6)	19 Jan 2021 05:13:41
	Mikayla Frye (b) (4)	20 Aug 2020 20:27:35
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'as needed (PRN)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '19 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:27:35

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Oct 2020 13:34:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:34:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:30:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:30:22
Data point term sent to Coder	System	20 Aug 2020 20:29:28
User entered 'vitamin B'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	11 Nov 2020 15:51:25
User closed query 'Per DM CLR: Note, Indication = HEALTH PROMOTION. Please review and mark 'Prophylaxis'. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Note, Indication = HEALTH PROMOTION. Please review and mark 'Prophylaxis'. Update Con Med eCRF as appropriate.' answered with 'data correct as entered' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:44:29
User opened query 'Per DM CLR: Note, Indication = HEALTH PROMOTION. Please review and mark 'Prophylaxis'. Update Con Med eCRF as appropriate.' (Site from DM).	Joan Siegner (b) (4)	30 Sep 2020 16:19:15
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 15:59:25
	Mikayla Frye (b) (4)	20 Aug 2020 20:28:32
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Health promotion'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:58:26
Query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'dosage unknown; self-reported' (Site from DM).	Joan Siegner (b) (4)	30 Sep 2020 16:19:25
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 15:59:21
User entered 'tablet (TABLET)'	Mikayla Frye (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'other (OTHER)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '3 times per week'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:54:56
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 with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4)	20 Aug 2020 20:33:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:28:32
User entered 'un UNK 2016'	Mikayla Frye (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
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)	02 Oct 2020 18:02:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 18:02:51
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4)	02 Oct 2020 18:02:20 02 Oct 2020 18:01:36
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)	20 Aug 2020 20:31:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 20:31:17
Data point term sent to Coder User entered 'Albuterol'	System Mikayla Frye (b) (4)	20 Aug 2020 20:30:29 20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Seasonal allergies'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per DM CLR: Please review the dose of this medication and update the Dose field to indicate the actual dose administered instead of dose range. Update eCRF as appropriate.' (Site from DM).	(b) (4)	05 Oct 2020 09:44:41
Query 'Per DM CLR: Please review the dose of this medication and update the Dose field to indicate the actual dose administered instead of dose range. Update eCRF as appropriate.' answered with 'exact dose unknown, self reported' (Site from DM).	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Please review the dose of this medication and update the Dose field to indicate the actual dose administered instead of dose range. Update eCRF as appropriate.' (Site from DM).	Heather Douds (b) (4)	02 Oct 2020 18:01:28
User entered '1-2'	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 04:20:08
	Mikayla Frye (b) (4)	20 Aug 2020 20:29:36
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'puff (PUFF)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'as needed (PRN)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per DM CLR: Please review Route field if INHALATION is more appropriate route for this medication. Update as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review Route field if INHALATION is more appropriate route for this medication. Update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:44:48
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Oct 2020 18:01:40
User opened query 'Per DM CLR: Please review Route field if INHALATION is more appropriate route for this medication. Update as appropriate.' (Site from DM).	(b) (4)	
User entered 'Nasal (NASAL)'	Heather Douds (b) (4)	02 Oct 2020 18:01:36
	(b) (4), (b) (6)	02 Oct 2020 04:20:00
	Mikayla Frye (b) (4)	20 Aug 2020 20:29:36
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System (b) (4)	21 Aug 2020 05:54:56
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 with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4)	20 Aug 2020 20:33:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:29:36
User entered 'un UNK 2012'	Mikayla Frye (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:29:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: NASACORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 22:07:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 22:07:17
Data point term sent to Coder	System	21 Aug 2020 22:06:30
Coding entries removed.	Heather Douds (b) (4)	21 Aug 2020 22:06:00
User entered 'NASACORT' reason for change: Data Entry Error	Heather Douds (b) (4)	21 Aug 2020 22:06:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: NASACORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 10:21:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 10:21:13
Data point term sent to Coder	System	20 Aug 2020 20:33:39
User entered 'Nasacort HD'	Mikayla Frye (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Seasonal allergies'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '55'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'ug (ug)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'as needed (PRN)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Nasal (NASAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. (Site from DM).' Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. answered with 'updated' (Site from DM).' User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. (Site from DM).' Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4), (b) (6) Heather Doubs (b) (4) (b) (4), (b) (6)	06 Oct 2020 12:26:24 05 Oct 2020 13:59:51 02 Oct 2020 04:21:08 21 Aug 2020 05:54:56
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 with 'Date is correct as entered.' (Site from System). 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). User entered 'un UNK 2012'	Mikayla Frye (b) (4) System Mikayla Frye (b) (4)	20 Aug 2020 20:33:42 20 Aug 2020 20:33:28 20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 12:45:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 12:45:16
Data point term sent to Coder	System	06 Oct 2020 12:44:14
User entered 'zoloft'	Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'depression'	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '50'	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '28 Sep 2020'	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening BILE REFLUX should be recorded, and update con med indication or provide clarification. ' (Site from DM). Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening BILE REFLUX should be recorded, and update con med indication or provide clarification. ' answered with 'not worsening, typical bile reflux' (Site from DM).	(b) (4) (b) (4), (b) (6) Cassandra Zehenny (b) (4) (b) (4)	17 Nov 2020 07:21:11 12 Nov 2020 21:13:28
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening BILE REFLUX should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:56:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 00:21:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 00:21:24
Data point term sent to Coder	System	12 Oct 2020 17:56:08
User entered 'pepcid'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'bile reflux'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 07:22:22
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'done' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	12 Nov 2020 21:12:55
User entered '20' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	12 Nov 2020 21:12:51
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:56:00
User entered '1'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4) Cassandra Zehenny (b) (4)	12 Nov 2020 21:12:51
User entered 'tablet (TABLET)'	(b) (4) Stanley Doublin (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	10 Nov 2020 13:36:28
User entered '5 Oct 2020'	(b) (4)	
	Stanley Doublin (b) (4)	12 Oct 2020 17:55:46
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
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)	17 Nov 2020 15:15:50
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 15:15:50
Data point term sent to Coder	System	17 Nov 2020 15:14:34
User entered 'influenza vaccine'	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Yes (Y)'	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'prophylaxis'	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '.5'	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'mL (mL)'	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'once (ONCE)'	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '28 Oct 2020'	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '28 Oct 2020'	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User entered empty.	System	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User entered empty.	System	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:55:15
User entered empty.	System	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Feb 2021 16:50:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 16:50:29
Data point term sent to Coder	System	01 Feb 2021 16:49:07
Coding entries removed.	Cassandra Zehenny (b) (4)	01 Feb 2021 16:48:57
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Nov 2020 16:16:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 16:16:48
Data point term sent to Coder	System	17 Nov 2020 15:17:37
User entered 'levothyroxine'	Stanley Doublin (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per DM CLR: Previous response indicate data was updated; however, there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:12:36
Query 'Per DM CLR: Previous response indicate data was updated; however, there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Med history #12' (Site from DM).	Cassandra Zehenny (b) (4)	01 Feb 2021 16:49:05
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	01 Feb 2021 16:48:57
User opened query 'Per DM CLR: Previous response indicate data was updated; however, there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 08:29:48
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).		21 Jan 2021 11:30:32
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	Cassandra Zehenny (b) (4)	19 Jan 2021 22:35:11
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:31:18

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User entered 'hyperthyroidism'	Stanley Dublin (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '50'	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'ug (ug)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Frequency = ONCE DAILY, as the medication timeframe is only 1 day. Please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 05:14:34
Query 'Per DM CLR: Please review the Frequency = ONCE DAILY, as the medication timeframe is only 1 day. Please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' answered with 'updated frequency, data entry error' (Site from DM).	Heather Douds (b) (4) (b) (4)	04 Mar 2021 15:23:03
User opened query 'Per DM CLR: Please review the Frequency = ONCE DAILY, as the medication timeframe is only 1 day. Please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 07:13:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '27 Oct 2020'	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:53:44
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	04 Mar 2021 15:22:50
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4)	04 Mar 2021 15:22:50
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
	(b) (4)	
User entered 'No (N)'	Stanley Doublin (b) (4)	17 Nov 2020 15:17:24
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:53:44
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	04 Mar 2021 15:22:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	04 Mar 2021 15:22:50
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
	(b) (4)	
User entered '27 Oct 2020'	Stanley Doublin (b) (4)	17 Nov 2020 15:17:24
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 13:25:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 13:25:33
Data point term sent to Coder	System	19 Apr 2021 13:24:43
User entered 'ADDERALL' reason for change: Data Entry Error	Stanley Doublin (b) (4)	19 Apr 2021 13:24:21
User entered 'adderll'	Stanley Doublin (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'Attention deficit hyperactivity disorder'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered '20'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered '30 Mar 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:38:52
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:51:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 13:24:09

US3552103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:51:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:47:41
User closed query 'Per CDM: Thanks for the response. Please select appropriate response for the same.' (Site from DM).	(b) (4)	27 Aug 2020 06:18:13
Query 'Per CDM: Thanks for the response. Please select appropriate response for the same.' answered with 'Updated per query response' (Site from DM).	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4)	25 Aug 2020 14:53:16
User opened query 'Per CDM: Thanks for the response. Please select appropriate response for the same.' (Site from DM).	(b) (4)	25 Aug 2020 14:53:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'de error' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 12:33:45
User opened query 'Data is required. Please complete.' (Site from System).		25 Aug 2020 12:24:53
User entered empty; reason for change Data Entry Error		
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	20 Aug 2020 20:23:14
	(b) (4)	20 Aug 2020 20:23:07
	System	
	Mikayla Frye (b) (4)	20 Aug 2020 20:23:07
	(b) (4)	20 Aug 2020 20:22:54
	Mikayla Frye (b) (4)	
	(b) (4)	

US3552103

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:51:43

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered '21 Sep 2020'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:57:51

US3552103

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:51:43

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'AE (specify) (ADVERSE EVENT)'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:57:51

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:51:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:12
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:47:41
User entered 'AE #1' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	19 Nov 2020 19:10:40
User entered 'AE - worsening depression'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:57:51