

US3552103 (Prod: Saint Louis University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:35:31

All time stamps listed in this document are displayed in GMT

US3552103

Form: Participant Creation

Generated On: 26 Nov 2020 09:35:31

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:35:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:35:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

Condition	CERVICAL DISCS REPLACED
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:35:31

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN AUG 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:35:31

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN DEC 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:35:31

Condition	ALLERGY TO MORPHINE
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:31

Condition	ANXIETY WITH HEIGHTS
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

Condition	BILE REFLUX
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

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

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Date of assessment (<i>dd MMM yyyy</i>)	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 (<i>dd MMM yyyy</i>)	UN AUG 2008
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>) _____	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

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

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	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 ☒ Axillary ☐ Other ☐
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)

Generated On: 26 Nov 2020 09:35:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	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 ☒ Axillary ☐ Other ☐
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

Generated On: 26 Nov 2020 09:35:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 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

Generated On: 26 Nov 2020 09:35:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	20 AUG 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 09:35:31

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 26 Nov 2020 09:35:31

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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: 26 Nov 2020 09:35:31

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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

Generated On: 26 Nov 2020 09:35:31

Was Contact Attempted?

Yes ☒

No ☐

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

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

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

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 09:35:31

Timepoint	Pre-Dose ☐
	Post-Dose ☒
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	

US3552103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to ☐
Adverse Event ☐
Physician withheld dose due to ☐
Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☒
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by ☐
Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

Generated On: 26 Nov 2020 09:35:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	21 SEP 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3552103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3552103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:28 (24 HR)
Collection date and time (derived)	23 OCT 2020 10:28

US3552103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
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 ☒ Yes ☐
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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2020 00:01

[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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 369

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 446

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 09:35:31

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 09:35:31

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 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: 26 Nov 2020 09:35:31

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
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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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

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06 APR 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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22 JUN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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29 JUN 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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06 JUL 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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13 JUL 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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20 JUL 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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27 JUL 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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10 AUG 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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17 AUG 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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20 AUG 2022 00:01

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24 AUG 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

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31 AUG 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

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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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07 SEP 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

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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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14 SEP 2022 23:59

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3552103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

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

Generated On: 26 Nov 2020 09:35:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552103

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:35:31

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3552103

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:35:31

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552103

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:35:31

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)

Generated On: 26 Nov 2020 09:35:31

AEID

Adverse event

WORSENING DEPRESSION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

03 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

v6.020 DTW (1102)

310 of 1518

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:35:31

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)

Generated On: 26 Nov 2020 09:35:31

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 ☐ Intramuscular ☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2004
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:31

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 ☐ Intramuscular ☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:31

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

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:31

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 ☐ Intramuscular ☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:31

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

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHES AND NECK MUSCLE PAIN
Dose per administration	300
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

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

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:31

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	
Route of administration	3 TIMES PER WEEK Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:35:31

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 ☐ Intramuscular ☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:35:31

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

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:35:31

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 ☐ Intramuscular ☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:35:31

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

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:35:31

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 ☐ Intramuscular ☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:35:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:35:31

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 ☐ Intramuscular ☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:35:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:35:31

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 ☐ Intramuscular ☒

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:35:31

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

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:35:31

Name of Medication	LEVOTHYROIXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTHYROIDISM
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 ☐ Intramuscular ☐

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:35:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		
27 OCT 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3552103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:35:31

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3552103

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:31

Date of dosing discontinuation (dd MMM yyyy)

21 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☒

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

AE #1

US3552103

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:35:31

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3552103 (Prod: Saint Louis University)

US3552103

Form: Participant Creation

Generated On: 26 Nov 2020 09:35:31

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3552103'	RWS_ENDPOINT ENDPOINT (b) (4) 	20 Aug 2020 16:44:43

US3552103

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:04:52

US3552103

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 16:44:44

US3552103

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:04:52

US3552103

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	20 Aug 2020 20:04:52

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered (b) (6) 1969'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 16:44:45

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Age](#)

Audit	User	Time (GMT)
User entered '51'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '51'	System	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Sex](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:05:20
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).	System	20 Aug 2020 20:05:15
User entered empty.	Mikayla Frye (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[White](#)

Audit	User	Time (GMT)
User entered '1'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

Unknown

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:15

US3552103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Cassandra Zehenny (b) (4)	20 Aug 2020 17:33:53
	(b) (4)	

US3552103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '2020'	System	20 Aug 2020 17:33:53

US3552103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Cassandra Zehenny (b) (4)	20 Aug 2020 17:33:53
	(b) (4)	

US3552103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	20 Aug 2020 17:33:53
	(b) (4)	

US3552103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	Cassandra Zehenny (b) (4)	20 Aug 2020 17:33:53
	(b) (4)	

US3552103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Cassandra Zehenny (b) (4)	20 Aug 2020 17:33:53
	(b) (4)	

US3552103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Aug 2020 17:33:53
	(b) (4)	

US3552103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 16:44:44

US3552103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:34:01

US3552103

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	20 Aug 2020 17:34:01
	(b) (4)	

US3552103

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:35:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:39

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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)	20 Aug 2020 20:05:57
	(b) (4)	

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Un UNK 2001'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '2001'	System	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:05:57

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '2018'	System	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:06:17

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:02:52
User entered 'un UNK 2016'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:06:45

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	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) (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) (b) (4)	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '1980'	System	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:07:02

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
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

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'un May 2019'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '2018'	System	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'May 2019'	System	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Aug 2020 20:07:38

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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)	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)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'un Aug 2008'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'un Aug 2008'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Aug 2008'	System	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '2008'	System	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Aug 2008'	System	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '2008'	System	20 Aug 2020 20:08:06

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'un Dec 1994'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	20 Aug 2020 20:09:47
User entered 'No (N)' reason for change: Data Entry Error	Mikayla Frye (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)	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'un Dec 1994'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Dec 1994'	System	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '1994'	System	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Dec 1994'	System	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '1994'	System	20 Aug 2020 20:09:05

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '2003'	System	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:09:33

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joan Siegner (b) (4)	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '2017'	System	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:18:53

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: 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
	(b) (4)	

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '2017'	System	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 17:54:20

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '11:34'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:34'	System	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '65' in	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: 26 Nov 2020 09:35:31

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '207.2' lb	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: 26 Nov 2020 09:35:31

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 05:27:05
Query 'Data is required. Please provide.' answered with 'nd' (Site from System).	Mikayla Frye (b) (4)	20 Aug 2020 20:14:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 20:14:51
User entered empty.	System	20 Aug 2020 20:14:51
	Mikayla Frye (b) (4)	20 Aug 2020 20:14:51
	(b) (4)	

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:14:51

US3552103

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:15:07

US3552103

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:15:07

US3552103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

US3552103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

US3552103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

If No, what is the reason?

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

US3552103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

US3552103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN Aug 2008' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:13:45
User entered 'un UNK 2007'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

US3552103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

US3552103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

US3552103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:10:26

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

[Specify](#)

Audit	User	Time (GMT)
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

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:24

US3552103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:43

US3552103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:43

US3552103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:43

US3552103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	20 Aug 2020 20:19:43

US3552103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	20 Aug 2020 17:20:34

US3552103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 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) [REDACTED]	20 Aug 2020 17:20:34

US3552103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 17:20:34

US3552103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:55

US3552103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:55

US3552103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:55

US3552103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:55

US3552103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:19:55

US3552103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4)	21 Sep 2020 17:14:03
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:37:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:46:32

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:31

Height

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Weight

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Height

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Weight

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 09:35:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	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: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '11:34'	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: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:34'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
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)	23 Sep 2020 16:55:01
answered with 'NCS' (Site from System).	(b) (4)	
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)	20 Aug 2020 20:21:21
	(b) (4)	

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	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: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	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: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:31

[Height](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Weight

Audit	User	Time (GMT)
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 (2)

Generated On: 26 Nov 2020 09:35:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	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: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	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: 26 Nov 2020 09:35:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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)	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)	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:15'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
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)	23 Sep 2020 16:55:06
answered with 'NCS' (Site from System).	(b) (4)	
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)	20 Aug 2020 20:21:21
	(b) (4)	

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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 (2)

Generated On: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:21:21

US3552103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Was the physical examination performed?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:21:42

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	20 Aug 2020 17:48:27
	(b) (4)	

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Cassandra Zehenny (b) (4)	20 Aug 2020 17:48:27
	(b) (4)	

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered empty.	Cassandra Zehenny (b) (4)	20 Aug 2020 17:48:27
	(b) (4)	

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Cassandra Zehenny (b) (4)	20 Aug 2020 17:48:27
	(b) (4)	

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:45'	Cassandra Zehenny (b) (4)	20 Aug 2020 17:48:27
	(b) (4)	

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:45'	System	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Cassandra Zehenny (b) (4)	20 Aug 2020 17:48:27
	(b) (4)	

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 17:48:27

US3552103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:13

US3552103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:13

US3552103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:15'	Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:22:13

US3552103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	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: 26 Nov 2020 09:35:31

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:20'	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: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:22:26

US3552103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 19:41:04

US3552103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 19:41:04

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Aug 2020 18:16:38
User entered '96.7'	System	20 Aug 2020 18:16:38

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Aug 2020 02:10:48
User entered '97.1'	System	21 Aug 2020 02:10:48

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Aug 2020 17:46:25
User entered 'Yes (Y)'	System	21 Aug 2020 17:46:25

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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-cabde5b940e3' 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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 17:46:25
User entered '21 Aug 2020 12:46'	System	21 Aug 2020 17:46:25

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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-ea709962eaae'	System	22 Aug 2020 19:50:35
User entered 'Yes (Y)'	System	22 Aug 2020 19:50:35

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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-ea709962eaae'	System	22 Aug 2020 19:50:35
User entered '98.4'	System	22 Aug 2020 19:50:35

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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-ea709962eaae'	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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-ea709962eaae'	System	22 Aug 2020 19:50:35
User entered '22 Aug 2020 14:50'	System	22 Aug 2020 19:50:35

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:41:56
User entered '96.6'	System	23 Aug 2020 17:41:56

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:42:41
User entered 'Yes (Y)'	System	24 Aug 2020 18:42:41

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:42:41
User entered '96.0'	System	24 Aug 2020 18:42:41

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:42:41
User entered '24 Aug 2020 13:42'	System	24 Aug 2020 18:42:41

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:09
User entered 'Yes (Y)'	System	25 Aug 2020 21:33:09

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:09
User entered '96.6'	System	25 Aug 2020 21:33:09

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:09
User entered '25 Aug 2020 16:33'	System	25 Aug 2020 21:33:09

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	26 Aug 2020 20:19:27
User entered '97.1'	System	26 Aug 2020 20:19:27

US3552103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 17:39:34
User entered '21 Aug 2020 12:39'	System	21 Aug 2020 17:39:34

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:50:44', 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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:24
User entered '25 Aug 2020 16:33'	System	25 Aug 2020 21:33:24

US3552103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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'	System	21 Aug 2020 17:40:14
User entered 'None (0)'	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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'	System	21 Aug 2020 17:40:14
User entered 'None (0)'	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Aug 2020 17:40:14
User entered 'None (0)'	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	21 Aug 2020 17:40:14
User entered 'None (0)'	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Aug 2020 17:40:14
User entered 'None (0)'	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	21 Aug 2020 17:40:14
User entered 'None (0)'	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-21T12:40:09', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'd3853df5-7c51-4780-a2ea-6d9ac062cc6a'	System	21 Aug 2020 17:40:14
User entered 'No (N)'	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 17:40:14
User entered '21 Aug 2020 12:40'	System	21 Aug 2020 17:40:14

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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'	System	22 Aug 2020 19:51:21
User entered 'None (0)'	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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'	System	22 Aug 2020 19:51:21
User entered 'None (0)'	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	22 Aug 2020 19:51:21
User entered 'None (0)'	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	22 Aug 2020 19:51:21
User entered 'None (0)'	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	22 Aug 2020 19:51:21
User entered 'None (0)'	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	22 Aug 2020 19:51:21
User entered 'None (0)'	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-22T14:51:13', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7ecb28c1-a8f0-4648-9600-383dabeb8f6c'	System	22 Aug 2020 19:51:21
User entered 'No (N)'	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 19:51:21
User entered '22 Aug 2020 14:51'	System	22 Aug 2020 19:51:21

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:42:49
User entered 'None (0)'	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:42:49
User entered 'None (0)'	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:42:49
User entered 'None (0)'	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:42:49
User entered 'None (0)'	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:42:49
User entered 'None (0)'	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-23T12:42:40', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: 'b8b8bfc6-000a-439d-9c75-0b349eed5bbb'	System	23 Aug 2020 17:42:49
User entered 'No (N)'	System	23 Aug 2020 17:42:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:43:49
User entered 'None (0)'	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:43:49
User entered 'None (0)'	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:43:49
User entered 'None (0)'	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:43:49
User entered 'None (0)'	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:43:49
User entered 'None (0)'	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:43:49
User entered 'None (0)'	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:43:49
User entered '24 Aug 2020 13:43'	System	24 Aug 2020 18:43:49

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:52
User entered 'None (0)'	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:52
User entered 'None (0)'	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:52
User entered 'None (0)'	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:52
User entered 'None (0)'	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:52
User entered 'None (0)'	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:52
User entered 'None (0)'	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (456B7C2C-84ED-44C2-9FB2-18A42B0EECA7)', Time: '2020-08-25T16:33:43', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '00ffb9c4-5799-4f95-8a55-f50c65a22219'	System	25 Aug 2020 21:33:52
User entered 'No (N)'	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	25 Aug 2020 21:33:52
User entered '25 Aug 2020 16:33'	System	25 Aug 2020 21:33:52

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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'	System	26 Aug 2020 20:20:12
User entered 'None (0)'	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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'	System	26 Aug 2020 20:20:12
User entered 'None (0)'	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	26 Aug 2020 20:20:12
User entered 'None (0)'	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	26 Aug 2020 20:20:12
User entered 'None (0)'	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	26 Aug 2020 20:20:12
User entered 'None (0)'	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	26 Aug 2020 20:20:12
User entered 'None (0)'	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	26 Aug 2020 20:20:12
User entered '26 Aug 2020 15:20'	System	26 Aug 2020 20:20:12

US3552103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 19:41:18

US3552103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	27 Aug 2020 19:41:18

US3552103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	03 Sep 2020 21:14:56

US3552103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:14:56

US3552103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 13:35:25
User entered '3 Sep 2020'	Mikayla Frye (b) (4)	03 Sep 2020 21:15:05

US3552103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:48:35

US3552103

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 12:48:35

US3552103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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).	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: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	22 Sep 2020 12:48:43

US3552103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 12:48:43

US3552103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:51:22

US3552103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 12:51:22

US3552103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:51:34

US3552103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:51:34

US3552103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	22 Sep 2020 12:51:34

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Dublin (b) (4)	22 Sep 2020 12:52:07
	(b) (4)	

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	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: 26 Nov 2020 09:35:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:05'	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: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '129'	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: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '91'	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: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 12:52:07

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	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: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:52:20

US3552103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:37

US3552103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:52:37

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'As a reminder - please complete the Dosing Disc eCRF. ' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 15:22:56
Query 'As a reminder - please complete the Dosing Disc eCRF. ' answered with 'done' (Site from CRA).	Heather Douds (b) (4)	23 Sep 2020 16:58:02
User opened query 'As a reminder - please complete the Dosing Disc eCRF. ' (Site from CRA).	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 15:46:43
	Stanley Doublin (b) (4)	22 Sep 2020 12:55:54
	(b) (4)	

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

If No, reason not given

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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)	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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	23 Sep 2020 15:52:35
User entered 'worsening depression'	Stanley Dublin (b) (4)	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:55:54

US3552103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 12:56:52

US3552103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	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: 26 Nov 2020 09:35:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	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: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	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: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 12:57:05

US3552103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 12:05:02

US3552103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 12:05:02

US3552103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 12:05:13

US3552103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 12:05:13

US3552103

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 12:41:47

US3552103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 13:35:43
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	06 Oct 2020 12:41:55

US3552103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 17:52:52

US3552103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 17:53:14

US3552103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:47

US3552103

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:37:47

US3552103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:37:54

US3552103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	23 Oct 2020 16:37:54

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:37:58

US3552103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:38:02

US3552103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:38:18

US3552103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:38:18

US3552103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:28'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:38:18

US3552103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Nov 2020 15:09:52

US3552103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:09:52

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[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: '2020-10-23T10:40:32', 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: 26 Nov 2020 09:35:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[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: '2020-10-27T00:06:23', 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: 26 Nov 2020 09:35:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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: '2020-11-06T04:48:59', 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

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-17T00:01:49', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7def7a5a-8d02-4c1d-baa6-5ca6688c77cd'	System	17 Nov 2020 06:06:19
User entered 'No (N)'	System	17 Nov 2020 06:06:19

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1425723-D52E-46E6-B7B7-B092E29C0002)', Time: '2020-11-17T00:04:40', User OID: 'PatientReportedOutcome (US3552103)', ODM File OID: '7def7a5a-8d02-4c1d-baa6-5ca6688c77cd'	System	17 Nov 2020 06:06:19
User entered 'No (N)'	System	17 Nov 2020 06:06:19

US3552103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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: '2020-11-17T00:06:12', 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: 26 Nov 2020 09:35:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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 Oct 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: 26 Nov 2020 09:35:31

[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 Oct 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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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 Oct 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: 26 Nov 2020 09:35:31

[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 Oct 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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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 Oct 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: 26 Nov 2020 09:35:31

[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 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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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 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: 26 Nov 2020 09:35:31

[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 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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:53:40
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 23:53:40

US3552103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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 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: 26 Nov 2020 09:35:31

[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 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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Nov 2020 15:10:09

US3552103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	17 Nov 2020 15:10:09

US3552103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	17 Nov 2020 15:10:09

US3552103

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:35:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:58:17

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Adverse event](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '03 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 13:36:09
User entered '3 Sep 2020'	Heather Douds (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	17 Nov 2020 15:11:13
User entered 'Yes (Y)'	Heather Douds (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	17 Nov 2020 15:11:13
User entered empty.	Heather Douds (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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).	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)	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)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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 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

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 15:38:18
Query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	19 Nov 2020 15:15:37
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 15:15:31
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	Heather Douds (b) (4)	23 Sep 2020 19:45:26
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Heather Douds (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[None](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	17 Nov 2020 15:11:13
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 17:05:08

US3552103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 17:05:08

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:35:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	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)	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'depression'	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: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '450' reason for change: New Information	Mikayla Frye (b) (4)	03 Sep 2020 21:15:52
User entered '300'	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: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:35:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:24:39

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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) (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: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Irritable bowel syndrome'	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: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	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: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:35:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:25:36

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	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)	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)	20 Aug 2020 20:26:48
	(b) (4)	

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
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) (b) (4)	20 Aug 2020 20:26:48

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	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: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:35:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: 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	17 Nov 2020 15:46:18
	Heather Douds (b) (4)	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	20 Aug 2020 20:28:25
	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: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
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. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 13:07:49
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. ' answered with 'Will clarify on day 85 call' (Site from DM).	(b) (4)	
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. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:15:29
User entered 'Headaches and muscle pain'	(b) (4), (b) (6)	22 Oct 2020 18:19:49
	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: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	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: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:35:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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 User entered 'vitamin B'	System Mikayla Frye (b) (4) (b) (4)	20 Aug 2020 20:29:28 20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	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), (b) (6)	05 Oct 2020 09:44:29
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).	Joan Siegner (b) (4)	30 Sep 2020 16:19:15
User opened query 'Per DM CLR: Note, Indication = HEALTH PROMOTION. Please review and mark 'Prophylaxis'. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 15:59:25
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Health promotion'	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: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
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) (b) (4)	20 Aug 2020 20:28:32

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered '3 times per week'	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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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) (b) (4)	02 Oct 2020 18:02:51
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (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) (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) (b) (4)	20 Aug 2020 20:31:17
Data point term sent to Coder User entered 'Albuterol'	System Mikayla Frye (b) (4) (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: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Seasonal allergies'	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: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
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), (b) (6)	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).	Heather Douds (b) (4)	02 Oct 2020 18:01:28
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).	(b) (4), (b) (6)	02 Oct 2020 04:20:08
User entered '1-2'	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: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'puff (PUFF)'	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: 26 Nov 2020 09:35:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
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), (b) (6)	05 Oct 2020 09:44:48
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).	Heather Douds (b) (4)	02 Oct 2020 18:01:40
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Oct 2020 18:01:36
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), (b) (6)	02 Oct 2020 04:20:00
User entered 'Nasal (NASAL)'	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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	21 Aug 2020 22:06:00
User entered 'NASACORT' reason for change: Data Entry Error	Heather Douds (b) (4) (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) (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) (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) (b) (4)	20 Aug 2020 20:33:28

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Seasonal allergies'	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: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '55'	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: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	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: 26 Nov 2020 09:35:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Nasal (NASAL)'	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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	06 Oct 2020 12:26:24
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).	Heather Douds (b) (4)	05 Oct 2020 13:59:51
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).	(b) (4), (b) (6)	02 Oct 2020 04:21:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.		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 20:33:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:33:28
User entered 'un UNK 2012'	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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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) (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 Dublin (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: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'depression'	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: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	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: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:35:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:35:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 12:43:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	17 Nov 2020 07:21:11
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).	Cassandra Zehenny (b) (4)	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)	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)	13 Oct 2020 00:21:24
Data point term sent to Coder	System	12 Oct 2020 17:56:08
User entered 'pepcid'	Stanley Dublin (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'bile reflux'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
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) (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)	12 Nov 2020 21:12:55
User entered '20' reason for change: Per Query Resolution	Cassandra Zehenny (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 Dublin (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	12 Nov 2020 21:12:51
User entered 'tablet (TABLET)'	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: 26 Nov 2020 09:35:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '05 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 13:36:28
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:35:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 17:55:46

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	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) (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) (b) (4)	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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
	(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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'prophylaxis'	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
	(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: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '.5'	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
	(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: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	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
	(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: 26 Nov 2020 09:35:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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
	(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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	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
	(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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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
	(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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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
	(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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '28 Oct 2020'	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) (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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
	(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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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
	(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: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	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
	(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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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
	(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: 26 Nov 2020 09:35:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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.	(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: 26 Nov 2020 09:35:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:35:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:14:02
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4) (b) (4)	17 Nov 2020 15:12:25
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 16:48:11

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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 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: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'hyperthyroidism'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	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: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	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: 26 Nov 2020 09:35:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (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: 26 Nov 2020 09:35:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:35:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:35:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 15:17:24

US3552103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:35:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Thanks for the response. Please select appropriate response for the same.' (Site from DM).	(b) (4), (b) (6)	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).	Heather Douds (b) (4)	25 Aug 2020 14:53:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	25 Aug 2020 14:53:05
User opened query 'Per CDM: Thanks for the response. Please select appropriate response for the same.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 12:33:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 12:24:53
Query 'Data is required. Please complete.' answered with 'de error' (Site from System).	Mikayla Frye (b) (4)	20 Aug 2020 20:23:14
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:23:07
User entered empty; reason for change Data Entry Error	Mikayla Frye (b) (4)	20 Aug 2020 20:23:07
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	20 Aug 2020 20:22:54

US3552103

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:31

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	Heather Douds (b) (4) (b) (4)	23 Sep 2020 16:57:51

US3552103

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User entered 'AE #1' reason for change: Data Entry Error	Heather Douds (b) (4)	19 Nov 2020 19:10:40
User entered 'AE - worsening depression'	Heather Douds (b) (4)	23 Sep 2020 16:57:51